KERAJAAN MALAYSIA & ANOR v. DR VIJAENDREH SUBRAMANIAM & ANOR

FEDERAL COURT, PUTRAJAYA
TENGKU MAIMUN TUAN MAT CJ
NALLINI PATHMANATHAN FCJ
NORDIN HASSAN FCJ
[CIVIL APPEAL NO: 01(f)-16-04-2024(W)]
3 MARCH 2025

Abstract – *(i) Registered medical practitioners, in seeking for declaratory orders as to whether they are entitled to dispense the drug Ivermectin to their patients for the purpose of medical treatment, are purely and entirely moving the court to exercise its most basic functions of judicial interpretation to determine the state of the law as regards the Poisons Act 1952, the Poisons Regulations 1952, the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984. Such declarations would assist them in clarifying their legal rights; it would not impede upon or interfere with any criminal investigations; (ii) It is not the courts but the Poisons Act 1952 (properly interpreted) that grants the right to registered medical practitioners to dispense Ivermectin as a Group B poison as it is a complete Code on all matters relating to poisons and was passed with the overt intention of regulating and overseeing all manner of dealings with poisons including their sale and supply. By virtue of ss. 19 and 21, there is an express exemption in favour of registered medical practitioners to dispense, in their professional judgment, Group B poisons for the treatment of their patients only. A prescription regime is also put in place to ensure that such dispensations or supplies are done in accordance with the law.*

CIVIL PROCEDURE: *Originating summons – Declaratory orders – Judicial interpretation – Seeking judicial interpretation of provisions – Whether registered medical practitioners entitled to dispense Ivermectin to patients under relevant provisions of Poisons Act 1952 ('Poisons Act') and Poisons Regulations 1952 ('1952 Regulations') – Whether registered medical practitioners only subjected to Poisons Act and 1952 Regulations – Whether registered medical practitioners ought to know their rights and position under law – Whether registered practitioners invited judicial interference upon executive policy by effectively legitimising Ivermectin for treatment of COVID-19*

CIVIL PROCEDURE: *Originating summons – Declaratory orders – Seeking judicial interpretation of provisions – Whether registered medical practitioners entitled to dispense Ivermectin to patients under relevant provisions of Poisons Act 1952 and Poisons Regulations 1952 – Whether originating summons would impede*

upon possible criminal investigations – Whether utility of declaratory orders to inform parties concerned 'exactly where they stand' and 'need not have to wait for something to happen before seeking court's protection' – Whether registered practitioners invited judicial interference upon executive policy by effectively legitimising Ivermectin for treatment of COVID-19

STATUTORY INTERPRETATION: *Construction of statutes – Judicial interpretation – Poisons Act 1952, ss. 18, 19 and 21 – Whether registered medical practitioners may sell, supply or administer any Group B poison to patients for medical treatment – Whether registered medical practitioners allowed to dispense Ivermectin to patients for purpose of patient's treatment – Whether Poisons Act 1952 ought to be read alone or must be read subject to other laws – Whether Poisons Act 1952 conferred specific rights unto registered medical practitioners – Whether registered medical practitioners subjected to provisions of Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984 – Whether subsidiary legislation could displace primary legislation*

WORDS & PHRASES: *'sale, supply or administration' – Poisons Act 1952 – Whether complete Code on all matters relating to poisons – Whether positively asserts right vested in ss. 18, 19 and 21 to registered medical practitioners to sell, supply and administer Group B poisons to patients for treatment – Whether registered medical practitioners may dispense drug Ivermectin to patient for treatment*

The core issue in this appeal concerned the interpretation of certain provisions in the Poisons Act 1952 ('Poisons Act') and the Poisons Regulations 1952 ('1952 Regulations'), as well as the Sale of Drugs Act 1952 ('Sale of Drugs Act') and its Regulations, namely the Control of Drugs and Cosmetics Regulations 1984 ('1984 Regulations'). On 14 June 2021, an investigating officer from the Selangor Pharmaceutical Services Division entered the second respondent's clinic and purchased a box of Ivermectin Verpin 12 tablets ('search and seizure'). As soon as the sale was completed, officers from the same department entered and confiscated from the second respondent's clinic tablets and capsules which were said to be Ivermectin medicines ('Ivermectin'). The items that were seized were chemically analysed and the Jabatan Kimia Malaysia confirmed that the items were indeed, Ivermectin. An investigation was done under the Poisons Act and the 1984 Regulations. Dissatisfied with the search and seizure, the two respondents jointly filed the originating summons ('OS') which gave rise to the present appeal. The first respondent, a qualified and registered medical practitioner, sued on behalf of himself and in the capacity of the Malaysian Association for the Advancement of Functional and Interdisciplinary Medicine ('MAAFIM'). The second respondent, a qualified and registered medical practitioner operating a clinic, was directly affected by the actions that were in question herein as it was his issued Ivermectin medications that were the subject of the search and seizure. The reliefs sought in the OS were,

inter alia; (i) a determination whether a registered medical practitioner is entitled to dispense Ivermectin as an ingredient to his or her patient under the Poisons Act read together with the 1952 Regulations; and (ii) a determination whether a registered medical practitioner can dispense Ivermectin to his or her patients for the purposes of the medical treatment of such patient only and in compliance with s. 19 of the Poisons Act and the 1952 Regulations. The respondents' case was that under the Poisons Act, it has long been the undisputed right of registered medical practitioners to dispense Group B poisons. The main thrust of the OS therefore sought definitive judicial interpretation of these provisions as against the provisions of the Sale of Drugs Act and the 1984 Regulations – which are the provisions on which the appellants rely. To add context to the thrust of their claim on interpretation, it was their case that the second respondent was entitled to dispense Ivermectin to his patients under the relevant provisions of the Poisons Act and its 1952 Regulations. The respondents' position was that Ivermectin was included in Group B of Part 1 of the Poisons List in the Poisons Act. In their submission, a cumulative reading of ss. 15, 18, 19 and 21 of the Poisons Act suggests that medical practitioners such as the respondents are expressly permitted to sell wholesale and retail Group B poisons for the use of their patients. The appellants, however, contended that by initiating this OS, the respondents have, in effect, sought to stymie or interfere with criminal process. The OS was effectively an invitation to the civil courts to make findings that ought to be made by the criminal courts on account of the fact that the second respondent has since been charged with an offence upon the search and seizure. On the merits, the appellants accepted that the sale of Ivermectin (either by retail or wholesale) and its dispensation is governed by the Poisons Act and the 1952 Regulations. However, in their submission, such a right should be construed together with the provisions of the Sale of Drugs Act and the 1984 Regulations. Upon the wholesome construction of these provisions, it was the appellants' case that the second respondent was not legally entitled to sell or dispense Ivermectin in the manner he says he is allowed to. It was the appellants' submission that as Ivermectin is a 'drug' per the definition in the Sale of Drugs Act, then by virtue of the 1984 Regulations, its sale, supply, importation, possession and administration must meet the cumulative requirements of reg. 7(1) of the 1984 Regulations, namely, that it must be a 'registered product' and that the second respondent must hold the appropriate licence required and issued under the 1984 Regulations. The appellants' primary contention was that the second respondent could not rely solely on the provisions of the Poisons Act and the 1952 Regulations as he and every other registered medical practitioner are subject to the provisions of the Sale of Drugs Act and its 1984 Regulations. The appellants further argued that upon fully construing the applicable provisions, and concluding that the second respondent could not

sell, dispense or administer Ivermectin, the OS would be seen as an attempt by the respondents to effectively advocate the use of Ivermectin as a suitable treatment for or preventive measure against COVID-19. This, the appellants submitted, was a question of executive and/or legislative policy and any attempt by the respondents to debate the merits of Ivermectin through the courts amounted to an invitation to judicial overreach on questions of policy. The High Court found that the declarations sought by the respondents did impede upon or interfere with any possible criminal investigations that may be brought against the second respondent and that the OS was an abuse of process and was frivolous. The Court of Appeal, however, held that the High Court erred and that the OS was not brought with a collateral purpose of interfering with the criminal investigations brought against him. The Court of Appeal found that a declaration of rights of a party could be requested from the courts before the event that the party was trying to avoid, occurs. The issues that arose herein were (i) whether the legal principles enunciated in *Datuk Syed Kechik v. Government Of Malaysia & Anor* (*'Syed Kechik'*) and *YAB Dato' Dr Zambry Abd Kadir & Ors v. YB Sivakumar Varatharaju Naidu (Attorney General Malaysia, Intervener)* (*'Zambry'*) apply to the situations or circumstances or cases where there were substantial issues or grievances regarding pending criminal investigation, criminality, criminal charges and prosecutorial discretion of the Public Prosecutor; (ii) whether a registered medical practitioner could sell (either by retail or wholesale) and/or dispense for purposes of consumption/administration by their human patients the substance Ivermectin (in whatever form) which was not a 'registered product' and without the benefit of a license for that purpose under the scheme enacted in the Poisons Act and the Sale of Drugs Act and their respective 1952 and 1984 Regulations; (iii) whether the Poisons Act could be read alone or must be read subject to other laws on the subject, in this case Sale of Drugs Act and its 1984 Regulations; and (iv) whether the respondents were inviting judicial interference upon executive policy by effectively legitimising the use of Ivermectin for the treatment of COVID-19.

Held (dismissing appeal)

Per Tengku Maimun Tuan Mat CJ delivering the judgment of the court:

(1) The very utility of declaratory orders is to inform parties concerned 'exactly where they stand' and that the affected party 'need not have to wait for something to happen before seeking the court's protection.' It had been the respondents' principal stance from day one that they were only subject to the Poisons Act and the 1952 Regulations in their dispensation of Ivermectin for the treatment of their patients only. As such, it was their submission that the declarations were not designed to impede upon or interfere with criminal investigations against the second respondent but rather, it was for them and all registered medical

practitioners to know their rights and position under the law. The respondents were not attempting to interfere with the criminal investigations to the extent of the relief prayed for in the declarations. (paras 66-70)

(2) The nature of the relief sought in this case was purely and entirely to move the court to exercise its most basic functions of judicial interpretation to determine the state of the law as regards the Poisons Act and the Sale of Drugs Act and their respective Regulations (1952 and 1984 Regulations). The respondents have not at all challenged the legality of the search and seizure nor have they suggested or asked for any relief to the effect that the second respondent ought not to be prosecuted or that he had not committed any offence. The first respondent represented a body of qualified specialists and doctors that have the right to determine the extent of the legal rights of all doctors to dispense Group B poisons and the extent of how such a right is limited, if at all, by the Sale of Drugs Act and the 1984 Regulations. (paras 71 & 72)

(3) It is only the courts that may make determinative findings of factual and legal rights. While it remains the Public Prosecutor's sole right to charge any person for an offence, such a power is exercised in accordance with written law. Where the law is unclear, it is only the courts who may finally determine the interpretation of that law or rule. Such a final determination would then also serve the effect of putting parties on notice on 'exactly where they stand' in terms of their present and future rights – as determined in *Syed Kechik.* While *Syed Kechik* and *Zambry* do not on their facts concern the grant of declarations pending criminal charges or investigations, their collective *ratio decidendi* extends to and applies *mutatis mutandis* to a case, such as this one, where the person(s) so affected seek(s) to the extent to clarify or determine his or their legal rights or position. The declarations did not impede upon or interfere with any criminal investigations and that the declarations would assist them in clarifying their legal rights *vis-à-vis* the Poisons Act and the Sale of Drugs Act and their attendant Regulations. Further, ss. 18, 19 and 21 of the Poisons Act themselves specifically contain procedures and principles which all registered medical practitioners must follow and to the extent that the criminal investigations relate to this, they remain open and unimpeded. Such declarations were not an abuse of process or frivolous and/or vexatious. (paras 73, 87, 88 & 89)

(4) Under s. 19(1)(a) of the Poisons Act, registered medical practitioners may issue Group B poisons to any person either by sale or supply (which would involve a financial transaction) or administer (which involves direct administration and personal supervision) all on the condition that

such a person is that registered medical practitioner's patient and that such 'sale, supply or administration' is for the treatment of that person as a patient. Section 21(2) (which section deals with Group B poisons) contains an entire procedure on prescriptions and how such poison (considered medication) is sold or supplied to the patient for the treatment of that patient. As such, because Ivermectin is classified as a Group B poison in the First Schedule (and it is not therefore a Group A poison), it would follow as per s. 19(1)(a) of the Poisons Act that any registered medical practitioner may sell, supply or administer Ivermectin to his patient for the treatment of his patient only and only by reason of the fact that the person so selling, supplying or administering Ivermectin is a registered medical practitioner. Under s. 19 of the Poisons Act, and having regard to the scheme of that Act, the second respondent (as are all other registered medical practitioners) is allowed by law to dispense Ivermectin to his patients provided that such dispensation is for the purposes of that patient's treatment only. The 1952 Regulations have little bearing on this interpretation because the rights to dispense (sell or supply) and administer Ivermectin as a Group B poison is substantively determined by the Poisons Act as the parent or primary legislation to the 1952 Regulations. Further, the 1952 Regulations deal more with technical matters mainly such as storing, labelling, packaging and import of poisons, and not with the substantive rights of registered medical practitioners that is regulated expressly by ss. 19 and 21 of the Poisons Act. (paras 105-109)

(5) Upon a wholesome analysis of the Poisons Act, it is a complete Code on all matters relating to poisons in the manner suggested in its preamble. The Poisons Act positively asserts a right vested in ss. 18, 19 and 21 to registered medical practitioners to sell, supply and administer Group B poisons to their patients for that patient's treatment only and specifically enumerates those poisons (and their manner of preparations) patently in the First Schedule. The Sale of Drugs Act appears to disregard any such mechanism for it is entirely silent on the rights of registered medical practitioners to supply 'drugs' (as opposed to expressly enumerated 'poisons') and what exactly can ostensibly be ascertained as 'drugs' in the absence of any expressly enumerated provisions in the Sale of Drugs Act. Thus, the Sale of Drugs Act has no application insofar as the present facts are concerned that is, in relation to the rights of a registered medical practitioner to sell, supply or administer Group B poisons as per ss. 18, 19 and 21 of the Poisons Act. As for the 1984 Regulations, its fate could be quickly decided since its parent Act, the Sale of Drugs Act had no nexus to the respondents in relation to Group B poisons. It is a tried and tested rule that subsidiary legislation cannot give or take away powers and rights that are conferred

by its parent Act or any other primary legislation. In this sense, the Poisons Act is a primary legislation whereas the1984 Regulations is only a subsidiary legislation and that too to the Sale of Drugs Act; not the Poisons Act. (paras 131-138)

(6) Just as the Sale of Drugs Act has no bearing on the aforementioned express rights conferred to registered medical practitioners by ss. 18, 19 and 21 of the Poisons Act, so too the 1984 Regulations (being a subsidiary legislation) could not purport to limit the application of the provisions of ss. 18, 19 and 21 of the Poisons Act – a primary legislation. While the Sale of Drugs Act is generally a legislation intended for a more specific purpose *ie*, the sale of drugs only as opposed to the wide purposes of all matters relating to poisons in the Poisons Act, ss. 18, 19 and 21 of the Poisons Act are nonetheless the more specific provisions that expressly confer specific rights unto registered medical practitioners to 'sell, supply and administer' Group B poisons to their patients for their treatment only which is a specific regime that the Sale of Drugs Act (despite its specificity) does not cater for. As for the 1984 Regulations, being a subsidiary legislation, they do not and could not have sufficient legal force to override the primary provisions of the Poisons Act's ss. 18, 19 and 21. (paras 145 & 147)

(7) The Government, perhaps rightly concerned about fallacious or suspicious treatment measures for COVID-19, was wary on the unproved use of Ivermectin. To curb its use, the Government took it upon itself to decide that the Sale of Drugs Act and its 1984 Regulations could be used as a means to restrict the right accorded to registered medical practitioners to dispense Group B poisons (including Ivermectin) as per the Poisons Act and to prevent any reliance on Ivermectin for the treatment and/or prevention of COVID-19. Unfortunately, their reliance on, and application of, the Sale of Drugs Act and the 1984 Regulations was erroneous and misplaced on all accounts of statutory construction. (paras 161 & 162)

(8) It is not the courts but the Poisons Act (properly interpreted) that grants the right to registered medical practitioners to dispense Ivermectin as a Group B poison and if they continue to do so in accordance with the Poisons Act, even if for the treatment/prevention of COVID-19, then this continues to happen because of the appellants' failure to enforce more suitable legal mechanisms to curb the practice pending any proper determination of Ivermectin's ability to treat or prevent COVID-19 as the respondents and others like them claim it can. To the extent that the appellants suggest that they may rely on the Sale of Drugs Act and the 1984 Regulations to disallow dispensation of Ivermectin under the Poisons Act, this court did not agree with that interpretation – and this had no bearing on any Government policy of Ivermectin as a drug/medicine/ingredient itself. (paras 167 & 168)

A ***Bahasa Melayu*** *Headnotes*

Isu teras dalam rayuan ini melibatkan tafsiran peruntukan-peruntukan tertentu dalam Akta Racun 1952 ('Akta Racun') dan Peraturan-Peraturan Racun 1952 ('Peraturan 1952'), serta Akta Jualan Dadah 1952 ('Akta Jualan Dadah') dan peraturannya, iaitu Peraturan-Peraturan Kawalan Dadah dan
B Kosmetik 1984 ('Peraturan 1984'). Pada 14 Jun 2021, seorang pegawai penyiasat dari Bahagian Perkhidmatan Farmaseutikal Selangor telah ke klinik responden kedua dan membeli sekotak tablet Ivermectin Verpin 12 ('pencarian dan penyitaan'). Sebaik sahaja jualan selesai, pegawai dari jabatan yang sama merampas tablet dan kapsul klinik responden kedua yang
C dikatakan sebagai ubat Ivermectin ('Ivermectin'). Barangan yang dirampas telah dianalisis dan Jabatan Kimia Malaysia mengesahkan bahawa barang tersebut sememangnya Ivermectin. Siasatan dijalankan bawah Akta Racun dan Peraturan 1984. Tidak berpuas hati dengan pencarian dan penyitaan, kedua-dua responden memfailkan saman pemula ('SP') yang menimbulkan
D rayuan ini. Responden pertama, seorang pengamal perubatan bertauliah dan berdaftar, menyaman bagi pihak dirinya dan atas kapasiti Persatuan Kemajuan Perubatan Fungsian dan Antara Disiplin Malaysia (MAAFIM). Responden kedua, seorang pengamal perubatan bertauliah dan berdaftar yang mengendalikan sebuah klinik, terjejas secara langsung oleh tindakan yang
E dipertikaikan di sini kerana ubat Ivermectin yang dikeluarkannya menjadi subjek pencarian dan penyitaan. Relief-relief yang dipohon dalam SP adalah, antara lain (i) penentuan sama ada pengamal perubatan berdaftar berhak untuk mendispensasi Ivermectin sebagai perubatan kepada pesakitnya bawah Akta Racun yang dibaca bersama dengan Peraturan 1952; dan (ii) penentuan
F sama ada pengamal perubatan berdaftar boleh mendispensasi Ivermectin kepada pesakitnya untuk tujuan rawatan perubatan pesakit tersebut sahaja dan mematuhi s. 19 Akta Racun dan Peraturan 1952. Adalah kes responden bahawa bawah Akta Racun, telah lama menjadi hak pengamal perubatan berdaftar yang tidak dipertikaikan untuk mendispensasi racun Kumpulan B. Oleh itu, teras utama SP mencari tafsiran kehakiman yang muktamad bagi
G peruntukan-peruntukan ini bertentangan dengan peruntukan Akta Jualan Dadah dan Peraturan 1984 – peruntukan yang menjadi sandaran perayu. Menambah konteks pada tuntutan teras mereka tentang tafsiran, adalah kes mereka bahawa responden kedua berhak memberikan Ivermectin kepada pesakitnya bawah peruntukan Akta Racun dan Peraturan 1952 yang
H berkaitan. Pendirian responden ialah Ivermectin termasuk dalam Kumpulan B Bahagian 1 Senarai Racun Akta Racun. Dalam hujahan mereka, bacaan terkumpul ss. 15, 18, 19 dan 21 Akta Racun mencadangkan pengamal perubatan seperti responden jelas dibenarkan menjual secara borong dan runcit racun Kumpulan B untuk kegunaan pesakit-pesakit mereka. Perayu,
I walau bagaimanapun, berpendapat bahawa dengan memfailkan SP ini, responden telah, secara efektifnya, menghalang atau mengganggu proses

jenayah. Saman pemula secara efektifnya adalah pelawaan buat mahkamah sivil untuk membuat dapatan yang sepatutnya dibuat oleh mahkamah jenayah kerana responden kedua telah didakwa dengan kesalahan semasa pencarian dan penyitaan. Atas merit, perayu menerima bahawa penjualan Ivermectin (sama ada secara runcit atau borong) dan dispensasinya dikawal oleh Akta Racun dan Peraturan 1952. Walau bagaimanapun, dalam hujahan mereka, hak tersebut harus ditafsirkan bersama dengan peruntukan Akta Jualan Dadah dan Peraturan 1984. Atas konstruksi peruntukan ini, adalah kes perayu bahawa responden kedua tidak berhak secara sah untuk menjual atau mendispensasi Ivermectin mengikut cara yang dia kata dia dibenarkan. Perayu-perayu berhujah bahawa memandangkan Ivermectin adalah 'perubatan' mengikut takrifan dalam Akta Jualan Dadah, maka menurut Peraturan 1984, penjualan, pembekalan, pengimportan, pemilikan dan pentadbirannya mesti memenuhi keperluan terkumpul Peraturan 7(1) Peraturan 1984 iaitu bahawa ia mestilah 'produk yang berdaftar' bawah responden dan responden kedua mesti memegang lesen yang sesuai yang diperlukan dan dikeluarkan bawah Peraturan 1984. Pertikaian utama perayu ialah responden kedua tidak boleh bergantung semata-mata pada peruntukan Akta Racun dan Peraturan 1952 kerana dia dan setiap pengamal perubatan berdaftar lain adalah tertakluk pada peruntukan-peruntukan Akta Jualan Dadah dan Peraturan 1984. Perayu-perayu selanjutnya berhujah bahawa apabila memahami sepenuhnya peruntukan yang terpakai, dan membuat kesimpulan bahawa responden kedua tidak boleh menjual, mengetepikan atau mentadbir Ivermectin, SP dilihat sebagai percubaan oleh responden untuk menyokong penggunaan Ivermectin sebagai rawatan yang sesuai untuk atau langkah pencegahan terhadap COVID-19. Apa yang dikemukakan oleh perayu-perayu adalah soal dasar eksekutif dan/atau perundangan dan apa-apa percubaan oleh responden untuk membicarakan merit Ivermectin melalui mahkamah adalah sama dengan pelawaan untuk melampaui batas kehakiman dari segi persoalan dasar. Mahkamah Tinggi mendapati bahawa pengisytiharan yang dipohon oleh responden telah menghalang atau mengganggu apa-apa kemungkinan penyiasatan jenayah yang mungkin dibawa terhadap responden kedua dan bahawa SP adalah satu penyalahgunaan proses dan remeh. Mahkamah Rayuan, bagaimanapun, berpendapat bahawa Mahkamah Tinggi tersilap dan bahawa SP tidak difailkan dengan tujuan untuk mengganggu siasatan jenayah yang dibawa terhadapnya. Mahkamah Rayuan mendapati pengisytiharan adalah hak sesuatu pihak untuk memohon daripada mahkamah sebelum kejadian yang cuba dielakkan oleh pihak itu berlaku. Isu-isu yang timbul di sini ialah (i) sama ada prinsip undang-undang yang dinyatakan dalam *Datuk Syed Kechik lwn. Kerajaan Malaysia & Anor* (*'Syed Kechik'*) dan *YAB Dato' Dr Zambry Abd Kadir & Ors lwn. YB Sivakumar Varatharaju Naidu (Peguam Negara Malaysia, pencelah)* (*'Zambry'*) terpakai kepada situasi atau keadaan atau kes di mana

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terdapat isu atau rungutan yang besar tentang penyiasatan jenayah, jenayah, pertuduhan jenayah dan budi bicara pendakwaan Pendakwa Raya yang belum selesai; (ii) sama ada pengamal perubatan berdaftar boleh menjual (sama ada secara runcit atau borong) dan/atau mendispensasi untuk tujuan penggunaan/pentadbiran oleh pesakit-pesakit manusia mereka bahan Ivermectin (dalam apa jua bentuk) yang bukan 'produk berdaftar' dan tanpa faedah lesen untuk tujuan itu bawah skim yang digubal dalam Akta Racun dan Akta Jualan Dadah serta Peraturan 1952 dan Peraturan 1984 masing-masing; (iii) sama ada Akta Racun boleh dibaca secara bersendirian atau mesti dibaca tertakluk kepada undang-undang lain mengenai perkara itu, dalam kes ini Akta Jualan Dadah dan Peraturan 1984; dan (iv) sama ada responden mengundang campur tangan kehakiman terhadap dasar eksekutif dengan membenarkan penggunaan Ivermectin untuk rawatan COVID-19.

Diputuskan (menolak rayuan)

Oleh Tengku Maimun Tuan Mat KHN menyampaikan penghakiman mahkamah:

(1) Kegunaan perintah pengisytiharan adalah untuk memaklumkan pihak berkenaan 'apakah pendirian mereka' dan pihak yang terjejas 'tidak perlu menunggu sesuatu berlaku sebelum mendapatkan perlindungan mahkamah.' Adalah menjadi pendirian utama responden-responden sejak mula lagi bahawa mereka hanya tertakluk kepada Akta Racun dan Peraturan 1952 dalam dispensasi Ivermectin untuk rawatan pesakit mereka sahaja. Oleh itu, adalah hujah mereka bahawa pengisytiharan itu tidak direka untuk menghalang atau mengganggu penyiasatan jenayah terhadap responden kedua tetapi sebaliknya, mereka dan semua pengamal perubatan berdaftar mengetahui hak dan kedudukan mereka bawah undang-undang. Responden-responden tidak cuba mengganggu penyiasatan jenayah setakat relief-relief yang dipohon dalam pengisytiharan.

(2) Sifat relief yang dipohon dalam kes ini adalah semata-mata dan sepenuhnya untuk menggerakkan mahkamah menjalankan fungsi tafsiran kehakiman yang paling asas untuk menentukan kedudukan undang-undang berkenaan Akta Racun dan Akta Jualan Dadah serta Peraturan -Peraturan masing-masing (Peraturan 1952 dan 1984). Responden-responden sama sekali tidak mencabar kesahihan pencarian dan penyitaan dan mereka juga tidak mencadangkan atau meminta apa- apa relief yang bermaksud bahawa responden kedua tidak patut didakwa atau dia tidak melakukan apa-apa kesalahan. Responden pertama mewakili badan pakar dan doktor-doktor bertauliah yang mempunyai hak untuk menentukan sejauh mana hak undang-undang semua doktor untuk mendispensasi racun Kumpulan B dan sejauh mana hak tersebut dihadkan, jika ada, oleh Akta Jualan Dadah dan Peraturan 1984.

(3) Hanya mahkamah yang boleh membuat dapatan penentu hak fakta dan undang-undang. Walaupun kekal sebagai hak tunggal Pendakwa Raya untuk mendakwa mana-mana orang atas kesalahan, kuasa sedemikian dilaksanakan mengikut undang-undang bertulis. Jika undang-undang tidak jelas, hanya mahkamah yang akhirnya boleh menentukan tafsiran undang-undang atau peraturan-peraturan itu. Penentuan muktamad sedemikian kemudiannya juga akan memberi kesan meletakkan pihak-pihak pada notis 'tepat pada pendirian mereka' dari segi hak mereka sekarang dan akan datang – seperti yang diputuskan dalam *Syed Kechik.* Walaupun *Syed Kechik* dan *Zambry* bukan kes berkaitan pemberian pengisytiharan sementara menunggu pertuduhan jenayah atau penyiasatan, *ratio decidendi* di situ secara kolektif meliputi dan menggunakan *mutatis mutandis* untuk kes, seperti yang ini, di mana orang-orang yang terjejas memohon setakat menjelaskan atau menentukan hak atau kedudukan undang-undangnya. Pengisytiharan itu tidak menghalang atau mengganggu mana-mana penyiasatan jenayah dan pengisytiharan itu akan membantu mereka dalam mendapat penjelasan hak undang-undang mereka melalui Akta Racun dan Akta Jualan Dadah serta Peraturan-Peraturan yang menyertainya. Selanjutnya, ss. 18, 19 dan 21 Akta Racun sendiri secara khusus mengandungi prosedur dan prinsip yang mesti dipatuhi oleh semua pengamal perubatan berdaftar dan setakat penyiasatan jenayah berkaitan dengan ini, tetap terbuka dan tanpa halangan. Pengisytiharan sedemikian bukanlah penyalahgunaan proses atau remeh dan/atau menyusahkan.

(4) Bawah s. 19(1)(a) Akta Racun, pengamal perubatan berdaftar boleh mendispensasi racun Kumpulan B kepada mana-mana orang sama ada melalui penjualan atau pembekalan (yang akan melibatkan transaksi kewangan) atau mentadbir (yang melibatkan pentadbiran langsung dan penyeliaan peribadi) semuanya tertakluk pada syarat bahawa orang tersebut adalah pesakit pengamal perubatan berdaftar itu dan bahawa 'penjualan, pembekalan atau pentadbiran' sedemikian adalah untuk rawatan orang itu sebagai pesakit. Seksyen 21(2) (bahagian mana yang berkaitan dengan racun Kumpulan B) mengandungi keseluruhan prosedur mengenai preskripsi dan bagaimana racun tersebut (dianggap perubatan) dijual atau dibekalkan kepada pesakit untuk rawatan itu. Oleh itu, kerana Ivermectin diklasifikasikan sebagai racun Kumpulan B dalam Jadual Pertama (dan oleh itu bukan racun Kumpulan A), ini akan mengikut s. 19(1)(a) Akta Racun bahawa mana-mana pengamal perubatan berdaftar boleh menjual, membekal atau mentadbir Ivermectin kepada pesakitnya untuk rawatan pesakitnya sahaja dan hanya kerana fakta bahawa orang yang menjual, membekal atau mentadbir Ivermectin adalah seorang pengamal perubatan berdaftar. Di bawah s. 19 Akta Racun, dan dengan mengambil kira skim Akta itu,

responden kedua (seperti semua pengamal perubatan berdaftar lain) dibenarkan oleh undang-undang untuk mendispensasi Ivermectin kepada pesakitnya dengan syarat dispensasi tersebut adalah untuk tujuan rawatan pesakit sahaja. Peraturan 1952 mempunyai sedikit kaitan dengan tafsiran ini kerana hak untuk mendispensasi (menjual atau membekalkan) dan mentadbir Ivermectin sebagai racun Kumpulan B secara substantif ditentukan oleh Akta Racun sebagai perundangan induk atau utama kepada Peraturan 1952. Selanjutnya, Peraturan 1952 lebih banyak berurusan dengan perkara teknikal terutamanya seperti menyimpan, melabel, membungkus dan mengimport racun, dan bukan dengan hak substantif pengamal perubatan berdaftar yang dikawal secara nyata oleh ss. 19 dan 21 Akta Racun.

(5) Berdasarkan analisis Akta Racun, ia adalah kod lengkap mengenai semua perkara yang berkaitan dengan racun mengikut cara yang dicadangkan dalam mukadimahnya. Akta Racun secara positif menegaskan hak yang diberikan dalam ss. 18, 19 dan 21 kepada pengamal perubatan berdaftar untuk menjual, membekal dan mentadbir racun Kumpulan B kepada pesakit mereka untuk rawatan pesakit itu sahaja dan secara khusus menyenaraikan racun tersebut (dan cara penyediaannya) secara paten dalam Jadual Pertama. Akta Jualan Dadah tidak menghiraukan mana-mana mekanisme sedemikian kerana ia senyap sepenuhnya mengenai hak pengamal perubatan berdaftar untuk membekalkan 'dadah' (berbanding dengan 'racun' yang dinyatakan secara jelas) dan apa sebenarnya yang boleh dipastikan sebagai 'dadah' jika tiada sebarang peruntukan yang dinyatakan dengan jelas dalam Akta Jualan Dadah. Oleh itu, Akta Jualan Dadah tidak diguna pakai setakat fakta semasa iaitu, berhubung dengan hak pengamal perubatan berdaftar untuk menjual, membekal atau mentadbir racun Kumpulan B mengikut ss. 18, 19 dan 21 Akta Racun. Untuk Peraturan 1984, Akta induknya, Akta Jualan Dadah, tidak mempunyai kaitan dengan responden berhubung racun Kumpulan B. Ini adalah peraturan yang telah dicuba dan diuji bahawa perundangan subsidiari tidak boleh memberi atau mengambil kuasa dan hak yang diberikan oleh Akta induknya atau mana-mana perundangan utama yang lain. Dalam pengertian ini, Akta Racun adalah perundangan utama manakala Peraturan 1984 hanyalah perundangan subsidiari dan itu juga kepada Akta Jualan Dadah; bukan Akta Racun.

(6) Sebagaimana Akta Jualan Dadah tidak mempunyai kaitan dengan hak nyata yang disebutkan di atas yang diberikan kepada pengamal perubatan berdaftar oleh ss. 18, 19 dan 21 Akta Racun, begitu juga Peraturan 1984 (sebagai perundangan subsidiari) tidak boleh bertujuan untuk mengehadkan pemakaian peruntukan ss. 18, 19 dan 21 Akta Racun – perundangan utama. Walaupun Akta Jualan Dadah secara

amnya adalah perundangan yang bertujuan untuk maksud yang lebih khusus iaitu, penjualan dadah hanya bertentangan dengan tujuan luas semua perkara yang berkaitan dengan racun bawah Akta Racun, ss. 18, 19 dan 21 Akta Racun adalah peruntukan yang lebih khusus yang secara nyata memberikan hak khusus kepada pengamal perubatan berdaftar untuk 'menjual, membekal dan mentadbir' racun Kumpulan B kepada pesakit mereka untuk rawatan mereka sahaja yang adalah rejim khusus yang tidak dipenuhi oleh Akta Jualan Dadah (walaupun kekhususannya). Bagi Peraturan 1984, sebagai perundangan subsidiari, mereka tidak ada dan tidak boleh mempunyai kuasa undang-undang yang mencukupi untuk mengatasi peruntukan utama Akta Racun melalui ss.18, 19 dan 21.

(7) Kerajaan yang betul-betul mengambil berat tentang langkah-langkah rawatan yang salah atau mencurigakan untuk COVID-19, berhati-hati terhadap penggunaan Ivermectin yang tidak terbukti. Untuk membendung penggunaannya, Kerajaan memutuskan bahawa Akta Jualan Dadan dan Peraturan 1984 boleh digunakan untuk menyekat hak yang diberikan kepada pengamal perubatan berdaftar untuk mendispensasi racun Kumpulan B (termasuk Ivermectin) mengikut Akta Racun dan untuk mengelakkan sebarang pergantungan kepada Ivermectin untuk rawatan dan/atau pencegahan COVID-19. Malangnya, pergantungan mereka pada, dan pemakaian, Akta Jualan Dadah dan Peraturan 1984, adalah salah pada konstruksi berkanun dalam apa jua keadaan.

(8) Bukan mahkamah tetapi Akta Racun (ditafsirkan dengan betul) yang memberi hak kepada pengamal perubatan berdaftar untuk mendispensasi Ivermectin sebagai racun Kumpulan B dan jika mereka terus berbuat demikian mengikut Akta Racun, walaupun untuk rawatan/pencegahan COVID-19, maka ini akan terus berlaku kerana kegagalan perayu untuk menguatkuasakan mekanisme undang-undang yang lebih sesuai untuk membendung amalan itu sementara menunggu apa-apa penentuan sewajarnya keupayaan Ivermectin untuk merawat atau mencegah COVID-19 seperti yang didakwa oleh responden dan orang lain seperti mereka. Setakat yang perayu mencadangkan bahawa mereka boleh bergantung kepada Akta Jualan Dadah dan Peraturan 1984 untuk tidak membenarkan dispensasi Ivermectin di bawah Akta Racun, mahkamah ini tidak bersetuju dengan tafsiran itu – dan ini tidak mempunyai kaitan dengan mana-mana dasar Kerajaan berkenaan Ivermectin sebagai dadah/perubatan/bahan itu sendiri.

Case(s) referred to:

Ang Ming Lee & Ors v. Menteri Kesejahteraan Bandar, Perumahan Dan Kerajaan Tempatan & Anor And Other Appeals [2020] 1 CLJ 162 FC ***(refd)***

Athvale v. New South Wales [2021] FCA 1075 ***(refd)***

Datuk Syed Kechik Syed Mohamed v. Government Of Malaysia & Anor [1978] CLJU 44; [1978] 1 LNS 44 FC ***(refd)***

Empayar Canggih Sdn Bhd v. Ketua Pengarah Bahagian Penguatkuasa Kementerian Perdagangan Dalam Negeri dan Hal Ehwal Pengguna Malaysia & Anor [2018] Supp MLJ 16 ***(refd)***

Government Of Malaysia v. Lim Kit Siang & Another Case [1988] 1 CLJ 219; [1988] 1 CLJ (Rep) 63 SC ***(refd)***

Kassam And Others v. Hazzard And Others [2021] 393 ALR 664 ***(refd)***

Lai Soon Onn v. Chew Fei Meng & Other Appeals [2018] 10 CLJ 48 CA ***(refd)***

Pihak Berkuasa Tatatertib Majlis Perbandaran Seberang Perai & Anor v. Muziadi Mukhtar [2020] 1 CLJ 1; [2020] 1 ILR 328 FC ***(refd)***

SD v. Royal Borough Of Kensington And Chelsea [2021] EWCOP 14 ***(refd)***

Tan Sri Haji Othman Saat v. Mohamed Ismail [1982] CLJU 2; [1982] 1 LNS 2 FC ***(refd)***

Tengku Jaffar Tengku Ahmad v. Karpal Singh [1993] 4 CLJ 183 HC ***(refd)***

Tey Por Yee & Anor v. Protasco Bhd & Other Appeals [2020] 5 CLJ 216 CA ***(refd)***

YAB Dato' Dr Zambry Abd Kadir & Ors v. YB Sivakumar Varatharaju Naidu; Attorney-General Malaysia (Intervener) [2009] 4 CLJ 253 FC ***(refd)***

Legislation referred to:

Control Of Drugs And Cosmetics Regulations 1984, rr. 7(1)(a), (1)(b), 15(1), (2)(c)

Federal Constitution, art. 145(1)

Poisons Act 1952, ss. 2, 6, 8, 9, 10, 11, 12(1)(c), 13, 15, 16, 17, 18(1)(c), 19(1)(a), 20, 21(1), (2), 22, 23, 26(1)

Sale of Drugs Act 1952, ss. 2, 12

For the appellants - Rahazlan Affandi Abdul Rahim; Liew Horng Binv & Saravanan Kuppusamy; SFCs

For the respondents - Gurdial Singh Nijar, Abraham Au Tian Hui & Lim Sze Han; M/s Yeoh Mazlina & Partners

Reported by Suhainah Wahiduddin

JUDGMENT

Tengku Maimun Tuan Mat CJ:

Introduction

[1] The core issue in this appeal concerns the interpretation of certain provisions in the Poisons Act 1952 (Act 366) and the Poisons Regulations 1952, as well as the Sale of Drugs Act 1952 (Act 368) and its regulations, namely the Control of Drugs and Cosmetics Regulations 1984. We shall respectively refer to them as: Act 366, the 1952 Regulations, Act 368, and the 1984 Regulations.

[2] The six questions upon which leave was granted ('leave questions'), are these:

Leave Question 1

Whether the legal principles enunciated in *Datuk Syed Kechik v. Government of Malaysia and Anor* [1979] 2 MLJ 101 and *YAB Dato' Dr Zambry bin Abd Kadir & Ors v. YB Sivakumar a/l Varatharaju Naidu (Attorney General Malaysia, Intervener)* [2009] 4 MLJ 24 apply to the situations or circumstances or cases where there are substantial issues or grievances regarding pending criminal investigation, criminality, criminal charges and prosecutorial discretion of the Public Prosecutor?

Leave Question 2

In the circumstances where the disputes canvassed by the applicant is on the registered medical practitioners' right to dispense Ivermectin to patients for the specific purpose of pandemic Covid-19 treatment, is it apt for the Court to only rely on the provisions of the Poisons Act 1952 [Act 366] and Poisons Regulations 1952 [1952 Regulations] and disregard the provisions of the Sales of Drugs Act 1952 [Act 368] and Control of Drugs and Cosmetics Regulations 1984 [1984 Regulations] in determining whether a registered medical practitioner is entitled to dispense Ivermectin to patients for the purpose of prophylaxis and/or medical treatment?

Leave Question 3

In the circumstances where at present, no product with Ivermectin as an active ingredient has been registered with the Drug Control Authority for human use and that it is the policy of the Government on the prohibition of Ivermectin for Covid-19 treatment, whether it is apt for the Court to directly or indirectly permit the use of an unregistered poison like Ivermectin including and not restricted to the treatment of Covid-19 which was contrary to the regulatory regime and framework of the Sales of Drugs Act 1952 [Act 368], Control of Drugs and Cosmetics Regulations 1984 [1984 Regulations], Poisons Act 1952 [Act 366] and Poisons Regulations 1952 [1952 Regulations]?

Leave Question 4

In the circumstances where to date, it is the Government's policy that the use of unregistered Ivermectin for the treatment of Covid-19 is only permitted for the purpose of clinical trials subject to the approval of the Ministry of Health which is then in line with the guidance of the World Health Organisation (WHO) and that clinical trials to establish the efficacy and effectiveness of Ivermectin in this regard have yet to be concluded, whether it is apt for the Court to directly or indirectly permit the use of an unregistered poison like Ivermectin including and not restricted to the treatment of Covid-19 which was contrary to the regulatory regime and framework of the Sales of Drugs Act 1952 [Act 368], Control of Drugs and Cosmetics Regulations 1984 [1984 Regulations], Poisons Act 1952 [Act 366] and Poisons Regulations 1952 [1952 Regulations]?

Leave Question 5

In the circumstances where the pandemic of Covid-19 gave rise to a public health emergency at a national and global level and that policy measures in respect of Covid-19 must necessarily be highly flexible, adapted based on every new development in scientific and medical knowledge, based on the collective experience of the world in dealing with a novel and deadly virus, whether it is apt for the Court to directly or indirectly permit the use of an unregistered poison like Ivermectin including and not restricted to the treatment of Covid-19 which was contrary to the regulatory regime and framework of the Sales of Drugs Act 1952 [Act 368], Control of Drugs and Cosmetics Regulations 1984 [1984 Regulations], Poisons Act 1952 [Act 366] and Poisons Regulations 1952 [1952 Regulations] and contrary to the Government's public health policy?

Leave Question 6

With the use and effect of the unregistered Ivermectin drugs still pending further clinical research at the World Health Organisation (WHO) with no assurance that Ivermectin could be used on human or to cure Covid-19, is it defying the interest of justice to legitimise the use of Ivermectin on human and dispensation of Ivermectin by registered medical profession under the Poisons Act 1952 [Act 366] and the Poisons Regulations 1952?.

[3] The largely undisputed background facts and circumstances which gave rise to this appeal are as follows.

Background

Search And Seizure Of Ivermectin

[4] On 14 Jun 2021, an investigating officer from the Selangor Pharmaceutical Services Division entered the second respondent's clinic and purchased from an assistant in that clinic a box of Ivermectin Verpin-12 tablets ('search and seizure').

[5] As soon as the sale was completed, officers from the same department entered and confiscated from the second respondent's clinic tablets and capsules which are said to be Ivermectin medicines ('Ivermectin').

[6] The items that were seized were chemically analysed and the Jabatan Kimia Malaysia confirmed, in a report dated 3 December 2021, that the items were indeed, Ivermectin. The investigation was said to be done under Act 366 and the 1984 Regulations.

The Originating Summons

[7] Dissatisfied with the search and seizure, the two respondents jointly filed the originating summons dated 21 September 2021 ('OS') which OS gives rise to the present appeal.

[8] The first respondent/plaintiff is a qualified and registered medical practitioner and was, at all material times, a specialist consultant doctor at Mahkota Medical Centre Sdn Bhd, at No. 3, Mahkota Melaka, Jalan Merdeka, 75000 Melaka. He sues on behalf of himself and in the capacity of the Malaysian Association for the Advancement of Functional and Interdisciplinary Medicine ('MAAFIM') for which he was, at the time, the President. MAAFIM is itself a lawful society registered under the Societies Act 1969.

[9] The second respondent is also a qualified and registered medical practitioner and operates a clinic under the name and style of Klinik Medik at 9156 Jalan Bandar 4, Taman Melawati, 53100 Kuala Lumpur. He is directly affected by actions that are in question in this case as it was his issued Ivermectin medications that were the subject of the Search and Seizure.

[10] The reliefs sought in the OS are these (in the National Language):

SAMAN PEMULA

(a) Pentafsiran peruntukan-peruntukan:

(i) Akta Racun 1952 termasuk seksyen 2, 12(1)(c), 18(1)(c), 19 dan 21(1) dan (2); dan

(ii) Peraturan-peraturan Racun 1952 termasuk Jadual Pertama Bahagian 1 Kategori B.

(b) Satu Penentuan sama ada seorang pengamal perubatan adalah berhak untuk mendispens (dispense) Ivermectin sebagai suatu bahan ramuan kepada pesakit-pesakitnya di bawah Akta Racun 1952 dibaca Bersama dengan Peraturan-peraturan Racun 1952.

(c) Satu Penentuan sama ada seorang pengamal perubatan boleh mendispens Ivermectin kepada pesakit-pesakitnya bagi tujuan rawatan perubatan pesakit tersebut sahaja dan selaras dengan seksyen 19 Akta Racun 1952 Peraturan-peraturan Racun 1952.

(d) Kos; dan

(e) Lain-lain relif yang mana Mahkamah Yang Mulia ini anggap sesuai, wajar dan adil, *inter alia*, bidang kuasa sedia ada Mahkamah yang Mulia ini.

[11] The English translation of the said reliefs is substantially the same but it indicates an additional prayer (d) not found in its National Language counterpart. For the avoidance of doubt, the English translation is reproduced, thus:

SAMAN PEMULA

(a) The interpretation of the provisions of:

(i) the Poisons Act 1952 including sections 2, 12(1)(c), 18(1)(c), 19 dan 21(1) and (2); and

(ii) the Poisons Regulations 1952 including the First Schedule Part I Category B.

A (b) A Determination whether a registered medical practitioner is entitled to dispense Ivermectin as an ingredient to his or her patient under the Poisons Act 1952 read together with the Poisons Regulations 1952.

(c) A Determination whether registered medical practitioner can dispense Ivermectin to his or her patients for the purposes of the medical treatment
B of such patient only and in compliance with section 19 of the Poisons Act 1952 and the Poisons Regulations 1952.

(d) Declarations, as appropriate, ensuing from the determinations and interpretation as aforesaid.

(e) Costs; and

C (f) Such further or other relief which this Honourable Court deems fit, appropriate and just to order under, *inter alia*, the inherent jurisdiction of this Honourable Court.

(emphasis added)

D **[12]** The difference between the two versions is that the English version contains an additional prayer (d) which we shall call the 'impugned prayer (d)'. This was a contention by the parties in the High Court and we shall refer to it where necessary, later.

E **[13]** Both parties accept that no criminal proceedings had been instituted against the first respondent as of the date of the filing of the OS. However, the appellants confirm that after the OS was filed, a criminal charge has been preferred against the second respondent.

[14] There is also no dispute that both respondents were at all material times registered medical practitioners within the meaning of s. 2 of the Act
F 366 and the Medical Act 1971, especially at the time the second respondent sold the Ivermectin to the investigating officer.

The Present Case

[15] For the avoidance of doubt, reference to Ivermectin will be made throughout this judgment, as has been in the judgments of the lower courts,
G as a 'poison'. It does not mean that Ivermectin or any other drug classified as a 'poison' in Act 366 is necessarily a poison in the ordinary understanding of the word poison such as perhaps rat poison is considered.

[16] Here, 'poison' is a legal term defined in s. 2 of the Act 366 as meaning:

H any substance specified by name in the first column of the poisons list and includes any preparation, solution, compound, mixture or natural substance containing such substance, other than an exempted preparation or an article or preparation included for the time being in the Second Schedule;

I **[17]** Anything so included in Act 366 is therefore a substance regulated by law and should be understood as a 'poison' in that sense.

[18] In general terms, the respondents' case is that under Act 366, it has long been the undisputed right of registered medical practitioners to dispense Group B poisons. The main thrust of the OS therefore seeks definitive judicial interpretation of these provisions as against the provisions of Act 368 and the 1984 Regulations – which are the provisions on which the appellants rely. To add context to the thrust of their claim on interpretation, it is their case that the second respondent was entitled to dispense Ivermectin to his patients under the relevant provisions of Act 366 and its 1952 Regulations.

[19] In their submissions, the respondents also suggest that the facts that give rise to the present OS originate from a circular issued by the Kuala Lumpur and Putrajaya Health Department ('JKWP') dated 9 August 2021 ('circular'), as follows:

JABATAN KESIHATAN WILAYAH PERSEKUTUAN
KUALA LUMPUR DAN PUTRAJAYA
Jalan Cenderasari
50590 KUALA LUMPUR
MALAYSIA

Tel : 03-2268 7333
Fax : 03-2268 7555
Laman Web : jkwkl.moh.gov.my

Ruj. Kami : Bil (2)dlm.JKWPKL/F/600-3/1/1 Jilid 2
Tarikh : 09 Ogos 2021

SEPERTI DALAM SENARAI EDARAN

Tuan / Puan,

MAKLUMAN BERKENAAN PENJUALAN/ PENGGUNAAN PRODUK *IVERMECTIN* SEBAGAI RAWATAN DAN PENCEGAHAN *COVID-19* DI MALAYSIA

Saya dengan segala hormatnya merujuk kepada perkara di atas.

2. Ketua Pengarah Kesihatan Malaysia telah mengeluarkan kenyataan akhbar pada 16 Mei 2021 berkaitan salah faham mengenai penggunaan racun *Ivermectin* sebagai rawatan dan pencegahan *Covid-19* di Malaysia.

3. Kementerian Kesihatan Malaysia ingin menasihatkan semua **pelesen/ Ahli Farmasi supaya tidak menjual secara runcit atau membekalkan secara borong** racun *Ivermectin* untuk tujuan rawatan *Covid-19* berikutan tiada data klinikal bagi membuktikan keberkesanan penggunannya dalam rawatan dan pencegahan *Covid-19*. Buat masa ini, pengimportan bahan mentah ivermectin bagi tujuan *compounding* untuk kegunaan manusia juga adalah tidak dibenarkan.

4. Bahagian Regulatori Farmasi Negara (NPRA) telah memaklumkan bahawa setakat ini **tiada produk** dengan bahan aktif *Ivermectin* yang berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD) untuk **kegunaan manusia**. Buat masa ini *World Health Organization* (WHO) hanya membenarkan *Ivermectin* sebagai rawatan *Covid-19* dalam **kajian/ percubaan klinikal sahaja**.

5. Oleh yang demikian, pihak tuan/puan adalah diarahkan untuk **memberhentikan segera** aktiviti perjualan, pembekalan dan pengiklanan sediaan mengandungi racun *Ivermectin* bagi rawatan dan pencegahan Covid-19 **jika ada**. Pemilikan/penjualan racun *Ivermectin* merupakan satu perlanggaran di bawah Peraturan 7(1)(a) Peraturan-peraturan Kawalan Dadah & Kosmetik 1984 yang merupakan satu kesalahan di bawah akta yang sama dan boleh dihukum dibawah Seksyen 12 Akta Jualan Dadah 1952.

6. Untuk makluman tuan/puan, di bawah Seksyen 26(1) Akta Racun 1952, Pegawai Pelesenan Negeri boleh dengan pertimbangannya untuk tidak mengeluarkan lesen atau membatalkan lesen yang telah dikeluarkan sebelum ini jika tuan/puan didapati melanggar undang-undang yang telah dikuatkuasakan.

[20] *Vide* the above circular, which was never addressed to the doctors but to pharmacies and pharmaceutical companies, the appellants did, through JKWP, state the following:

(i) the first appellant advised all registered/member pharmacies against selling by retail or supplying wholesale Ivermectin for the treatment of COVID-19 as there is no clinical data to prove its effects in treating or preventing COVID-19. For the material time, the import of raw materials of Ivermectin for the purpose of compounding for human consumption was also disallowed;

(ii) the National Pharmaceutical Regulatory Agency (NPRA) has informed that as at the material time, there is no product with Ivermectin as the active ingredient that has been registered with the Drug Control Authority (PBKD) for human consumption. At the material time, the World Health Organisation (WHO) allowed the use of Ivermectin as a treatment for COVID-19 in clinical/research trials only;

(iii) as such, the circular advises all addressees to immediately cease all activities relating to the sale, supply and marketing of the poison Ivermectin as treatment or prevention of COVID-19, if any such activities were carried out;

(iv) the circular goes on to advise that the possession and/or sale of Ivermectin amounts to a violation of reg. 7(1)(a) of the 1984 Regulations and which provision renders the same an offence punishable under s. 12 of Act 368; and

(v) the circular concludes that under s. 26(1) of Act 366, the State Licensing Officer may in his discretion refuse to issue or cancel any previously issued license if any of the circular's addressees are found to violate any of the laws in force.

[21] We come now to the relevant provisions. The primary provisions upon which the respondents rely are ss. 17, 19 and sub-s. 21(1) of Act 366, which they submit collectively taken together allow registered medical practitioners (such as the respondents) the right to dispense Group B poisons.

[22] Section 17 of Act 366 reads:

> Prohibition of sale to persons under 18
>
> 17. (1) No poison shall be sold or supplied to any person under eighteen years of age, otherwise than for purposes of the medical or dental treatment of such person.
>
> (2) Any person contravening this section shall be guilty of an offence against this Act.

(3) It shall be a sufficient defence to any charge under this section that the person charged had reasonable cause to believe that the person to whom such sale was made was above the age of eighteen years.

[23] Section 19 of Act 366 provides:

Supply of poisons for the purpose of treatment by professional men

19. (1) Any poison other than a Group A Poison may be sold, supplied or administered by the following persons for the following purposes:

(a) a registered medical practitioner may sell, supply or administer such poison to his patient for the purposes of the medical treatment of such patient only;

(b) a registered dentist Division I may sell, supply or administer such poison to his patient for the purposes of the dental treatment of such patient only; and

(c) a registered veterinary surgeon may sell or supply such poison to his client for the purposes of animal treatment only.

(2) A registered dentist Division II may sell, supply or administer to his patient for the purposes of the dental treatment of such patient only any poison other than a Group A or a Group B Poison.

(3) Every medicine containing any poison sold or supplied under subsection (1) or (2) shall be prepared by or under the immediate personal supervision of such registered medical practitioner, registered dentist or registered veterinary surgeon, as the case may be:

Provided that any medicine, received by such registered medical practitioner, registered dentist or registered veterinary surgeon in a prepared state from a manufacturer or wholesaler, shall be deemed, for the purposes of this section, to have been prepared by such registered medical practitioner, registered dentist or registered veterinary surgeon respectively, if the receptacle containing such medicine is labelled by or under the immediate personal supervision of such registered medical practitioner, registered dentist or registered veterinary surgeon in such manner as may be prescribed by regulations made under this Act, relating to the labelling of dispensed medicines.

(4) Any registered medical practitioner, registered dentist or registered veterinary surgeon who sells or supplies any poison or medicine containing a poison not prepared by him or under his immediate personal supervision shall be guilty of an offence against this Act.

[24] Subsection 21(1) of Act 366 which directly regulates Group B poisons then goes on to stipulate as follows:

A Group B Poisons

21. (1) Group B Poison shall not be sold or supplied by retail to any person except:

(a) where the sale or supply of such poison, if it had been a Group A Poison, would have been authorized under section 20;

B

(b) by a registered medical practitioner, registered dentist Division I or registered veterinary surgeon selling or supplying the same in accordance with section 19; or

(c) by a registered pharmacist, as a dispensed medicine on and in accordance with a prescription prescribed by a registered medical practitioner, registered dentist or registered veterinary surgeon in the form required by subsection (2) or (2A) and when supplied in accordance with this Act and of any regulations made thereunder relating to such sale or supply on a prescription.

C

D **[25]** In summary, the respondents' position is that Ivermectin is included in Group B of Part 1 of the Poisons List in Act 366. In their submission, a cumulative reading of ss. 15, 18, 19 and 21 of Act 366 suggests that medical practitioners such as the respondents are expressly permitted to sell wholesale and retail Group B poisons for the use of their patients.

E **[26]** This leads us to the appellants' case.

[27] The appellants' first contention is that by initiating this OS, the respondents have, in effect, sought to stymie or interfere with the criminal process. The OS is effectively an invitation to the civil courts to make findings that ought to be made by the criminal courts on account of the fact that the second respondent has since been charged with an offence upon the search and seizure.

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[28] Second, on the merits, the appellants accept that the sale of Ivermectin (either by retail or wholesale) and its dispensation are governed by Act 366 and the 1952 Regulations. However, in their submission, such a right should be construed together with the provisions of Act 368 and the 1984 Regulations. Upon the wholesome construction of these provisions, it is the appellants' case that the second respondent was not legally entitled to sell or dispense Ivermectin in the manner he says he is allowed to.

G

H **[29]** In support of this point, the appellants rely on s. 2 of Act 368, in particular, the following terms which have been defined thus:

In this Act, unless the context otherwise requires:

"drug" includes any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose;

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"medicinal purpose" means any of the following purposes:

(a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;

(b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;

(c) contraception;

(d) inducing anesthesia;

(e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;

(f) controlling body weight;

(g) general maintenance or promotion of health or wellbeing;

"sale" or "sell" includes barter and exchange and also includes offering or attempting to sell or causing or allowing to be sold or exposing for sale or receiving or sending or delivering for sale or having in possession for sale or having in possession any drug knowing that the same is likely to be sold or offered or exposed for sale.

[30] The appellants urge that s. 2 above must be read in conjunction with sub-regs. 7(1) and 15(1) of the 1984 Regulations which respectively stipulate that:

Regulation 7

Prohibition against manufacture, sale, supply, importation, possession and administration

7. (1) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administer any product unless:

(a) the product is a registered product; and

(b) the person holds the appropriate licence required and issued under these Regulations.

Regulation 15 Exemptions and savings

15. (1) ...

(2) The requirement of regulation 7(1) as regards a licence to supply or manufacture does not apply to the dispensing, of any drug for the purpose of it being used for medical treatment of a particular patient or animal, by the following persons and in the following circumstances:

(a) a pharmacist or a person working under the immediate personal supervision of a pharmacist in a retail pharmacy;

A (b) a person acting in the course of his duties who is employed in a hospital or dispensary maintained by the Federal or any State Government or out of public funds or by a charity approved for the purposes of section 9(1)(b) of the Poisons Ordinance 1952 or in an estate hospital and who is authorised in writing as provided in that section; and

B (c) a fully registered medical practitioner or a dental practitioner or a veterinary practitioner or a person working under the immediate personal supervision of such a practitioner if the drug in question is for the use of such practitioner or of his patients.

C **[31]** It is the appellants' submission that as Ivermectin is a "drug" per the definition in Act 368 then by virtue of the 1984 Regulations, its sale, supply, importation, possession and administration must meet the cumulative requirements of reg. 7(1) of the 1984 Regulations namely that it must be a "registered product" and that the second respondent must hold the appropriate licence required and issued under the 1984 Regulations.

D **[32]** The appellants' primary contention is that the second respondent cannot rely solely on the provisions of Act 366 and the 1952 Regulations as he and every other registered medical practitioner are subject to the provisions of Act 368 and its 1984 Regulations.

E **[33]** The appellants further argue that upon fully construing the applicable provisions, and concluding that the second respondent cannot sell, dispense or administer Ivermectin, the OS will be seen as an attempt by the respondents to effectively advocate the use of Ivermectin as a suitable treatment for or preventive measure against COVID-19. This the appellants F submit is a question of executive and/or legislative policy and any attempt by the respondents to debate the merits of Ivermectin through the courts amounts to an invitation to judicial overreach on questions of policy.

Decision/Analysis

G *The Main Issue And Other Preliminary Matters*

[34] We have in essence framed above the core arguments of parties in support and opposition to the basic propositions raised in this case. In the following parts of the judgment, we will address all remaining submissions and the decisions of the courts below as we come to decide them.

H **[35]** As we understand it from the facts and circumstances, the primary poser that falls for consideration in this case is ('main issue'):

> Can a registered medical practitioner sell (either by retail or wholesale) and/or dispense for purposes of consumption/administration by their human patients the substance Ivermectin (in whatever form) which is not I a 'registered product' and without the benefit of a license for that purpose under the scheme enacted in Acts 366 and 368 and their respective 1952 and 1984 Regulations.

[36] The facts in this OS also give rise to two additional issues. From what was summarised earlier, the first issue concerns the legal tenability of the nature of the declarations sought in this case and whether they can therefore be granted in light of the doctrine of separation of powers.

[37] The second issue that arises from the submission of the appellants also concerns the doctrine of separation of powers and it is whether the declarations, if granted, would tantamount to judicial interference with the executive and legislative policy by effectively accepting Ivermectin as a suitable treatment option or preventive measure for COVID-19.

The Legal Tenability Of The Declaratory Reliefs Sought

[38] Earlier, we reproduced the prayers sought in the OS in both their linguistic versions. However, we do not think it is necessary to venture into the dispute and which of the two versions (Malay and English versions) are authoritative.

[39] The reason for this is because the Court of Appeal only granted an order in terms of prayers (b) and (c) of the OS which are the same in both versions. The respondents only resist the appeal against the decision of the Court of Appeal and have not filed a cross-appeal to urge this court to grant prayers not considered and so they seem content with what the Court of Appeal has decided in their favour.

[40] For the avoidance of doubt, the Court of Appeal granted the following declaratory orders by answering the following two questions in the affirmative in para [84] of its judgment as follows ('declarations'):

> (a) Satu Penentuan sama ada seorang pengamal perubatan adalah berhak untuk mendispens (dispense) Ivermectin sebagai suatu bahan ramuan kepada pesakit-pesakitnya di bawah Akta Racun 1952 dibaca Bersama dengan Peraturan-Peraturan Racun 1952;
>
> (b) Satu Penentuan sama ada seorang pengamal perubatan boleh mendispens Ivermectin kepada pesakit-pesakitnya bagi tujuan rawatan perubatan pesakit tersebut sahaja dan selaras dengan seksyen 19 Akta Racun 1952 Peraturan-Peraturan Racun 1952.

[41] Henceforth, any references to declarations refer to the above two declarations which were granted by the Court of Appeal in favour of the respondents.

[42] From the High Court right up until the arguments before us, learned Senior Federal Counsel (SFC) for the appellants have maintained that the declarations in the nature sought exceed judicial power. Their submission is best captured in their own words, as follows:

A

2.4 In the light of the criminal investigation, the OS raised serious questions as to the jurisdiction of the Court. The Civil Court has no jurisdiction to determine questions of criminality and does not interfere with ongoing criminal investigation.

B

2.5 The purpose and effect of the Respondents' claim/OS is to pre-empt, impede and interfere with the ongoing criminal investigation against the 2nd Respondent by asking the Civil Court to determine the criminality *ie*, the dispensation of Ivermectin by medical practitioners to their patients for the treatment of Covid-19 is not a criminal offence.

C

[43] In support of this argument, the appellants place reliance on numerous judgments foremost of which include: *Government Of Malaysia v. Lim Kit Siang & Another Case* [1988] 1 CLJ 219; [1988] 1 CLJ (Rep) 63; [1988] 2 MLJ 12 ('*Lim Kit Slang*); *Lai Soon Onn v. Chew Fei Meng & Other Appeals* [2018] 10 CLJ 48; [2019] 2 MLJ 96 ('*Lai Soon Onn*'); *Tengku Jaffar Tengku Ahmad v. Karpal Singh* [1993] 4 CLJ 183; [1993] 3 MLJ 156 ('*Tengku Jaffar*); and

D

Empayar Canggih Sdn Bhd v. Ketua Pengarah Bahagian Penguatkuasa Kementerian Perdagangan Dalam Negeri dan Hal Ehwal Pengguna Malaysia & Anor [2018] Supp MLJ 16 ('*Empayar Canggih*').

[44] It is their submission that these judgments support the proposition that a declaration cannot be granted much less be entertained if the effect of the

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declaration is such that it impedes upon a criminal proceeding or enforces a matter which is rightly within the jurisdiction of the criminal courts.

[45] It is our view that the appellants are entirely correct on the law with respect to the nature and limitations of declaratory judgments. There are sound reasons grounded on policy as to why declarations cannot impede

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upon the criminal courts.

[46] Firstly, the power to institute, conduct and discontinue criminal proceedings is exclusively for the Public Prosecutor by virtue of art. 145(1) of the Federal Constitution. No private person has such a right. In other words, no private party may attempt to sue another private person for a

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declaration that seeks to condemn that other party for having committed an offence.

[47] Secondly, and as a natural consequence of the first, criminal proceedings are governed by entirely different considerations including a much higher standard of proof, *ie*, beyond a reasonable doubt. Civil

H

proceedings on the other hand, are decided on a balance of probabilities and to allow them to be used as a basis to find criminal liability would be in total violation of all principles known to criminal law including the right of a fair trial and the presumption of innocence.

I

[48] The cases cited by the appellants support these theories. In *Lim Kit Siang*, the respondent had sought (among other things) declarations to the effect that the then Prime Minister and two other Government Ministers had

engaged in corrupt practices. The Supreme Court held that such declarations were impermissible because they ought to be determined by the criminal courts and not the civil courts. Taking such a course was, in the words of Salleh Abas LP (at p. 27), likened to a prosecution done behind the Attorney General *cum* Public Prosecutor's back.

[49] In *Lai Soon Onn*, the plaintiffs had among other things sought declarations to the effect that the defendants had committed a criminal offence under the Capital Markets and Services Act 2007. In this regard, the Court of Appeal observed:

> [39] By the very nature of the declaratory reliefs prayed for, essentially the plaintiff seeks a declaration that the defendants committed a criminal offence under the CMSA. Before such a declaration can be made there must be a determination of a contravention. By filing his claim in the civil courts the plaintiff is seeking for such determination to be made by the civil court in a civil proceeding. Such cannot be the case. The burden of proof between the two is different. Essentially, it is not for the civil courts to intrude into the domain of the criminal court. That cannot be the intention of section 357 of the CMSA.

[50] Reference was also made to *Lim Kit Siang* to arrive at the same conclusion that declarations cannot be used in this way.

[51] The same is the case cited by the appellants in *Tengku Jaffar*, where Idris Yusoff J held in respect of the plaintiff's prayer for a declaration that the defendant's statement amounted to seditious libel, at p. 188 (CLJ); p. 164 (MLJ) as follows:

> In the circumstances, I agree with Mr Karpal Singh that the issues which relate to the alleged criminality do not come within the purview of a civil court as otherwise, the civil court might be accused of intruding into the domain of the criminal court. In the instant case, it is clear that the plaintiff has made a complaint to the wrong forum.

[52] The next authority cited by the appellants that warrants discussion is *Empayar Canggih*. The facts were briefly these.

[53] The appellants were suspected of having committed offences under the Optical Discs Act 2000 ('ODA 2000') and certain investigating officers from the Ministry of Trade and Consumer Affairs, acting on information received, seized machinery and equipment belonging to the appellants. The appellants then filed a judicial review application seeking writs of *mandamus* and *certiorari* against the Government alleging that such search and seizure was unlawful. By the time the judicial review came to be heard, the seized items had been returned and the appellants amended their claim to only include primarily declarations that such search and seizure was unlawful and damages on account of the same.

[54] The High Court dismissed the judicial review application principally on the grounds that the appellants' challenge ought to have been initiated by way of writ and not judicial review. This was upheld on appeal to the Court of Appeal. The sole question before the Federal Court was whether such a claim could have been commenced by way of judicial review.

[55] One of the many arguments raised before the Federal Court by the Government in *Empayar Canggih* was that their seizure of the machinery and equipment was lawful and permitted under the ODA 2000 in connection with investigations into the suspected commission of an offence under that Act. The Government's exercise of this statutory function was part of the investigation process of a law enforcement agency and as such was not an administrative decision that was amenable to judicial review.

[56] The present appellants rely on this judgment for their point that criminal investigations cannot be impeded upon, as indeed, this is what this court held in *Empayar Canggih*:

> [25] Similarly in the present appeal, the seizure was made in the course of a criminal investigation of an offence under Act 606 pursuant to the powers conferred under the Act. Such seizure clearly is not amenable to judicial review. The appellant was not without redress. It could have filed a private law writ action for damages. Indeed, s 48 of Act 606 provides for a cause of action for recovery of damages if a seizure is made without reasonable cause.
>
> [26] Our answer to the first leave question as modified by us therefore is that, a challenge to the exercise or a purported exercise of the power to seize the machinery and equipment in this case should be made by way of an ordinary private law action for damages.

[57] With the greatest of respect to the appellants, this authority is of no assistance to them. It is an accepted point of law that criminal investigations ought not to be impeded by abusing the law and legal process but other than that, *Empayar Canggih* only decided on the point that such an action could not proceed by way of judicial review. The decision affirms that criminal investigations can be challenged in an action for damages. Yet, whatever is the reasoning, the present appeal/OS is not grounded on a judicial review application but for declarations on certain rights, the respondents say they and other registered medical practitioners have under the law.

[58] The appellants raised these very arguments in the High Court and the said court accepted them based on most of the authorities cited above. The learned judge found that the declarations sought by the respondents did impede upon or interfere with any possible criminal investigations that may be brought against the second respondent. The learned judge went on to conclude that the OS was an abuse of process and was frivolous.

[59] The Court of Appeal, however, held that the learned judge erred in his assessment of the case; that the OS was not brought with a collateral purpose of interfering with the criminal investigations brought against him; and that the High Court had failed to appreciate the judgment of the former Federal Court in *Datuk Syed Kechik Syed Mohamed v. Government Of Malaysia & Anor* [1978] CLJU 44; [1978] 1 LNS 44; [1979] 2 MLJ 101 ('*Syed Kechik*') which case is also addressed before us in leave question 1.

[60] The Court of Appeal accepted the respondents' contention that *Syed Kechik* is the authority for the proposition that a declaration of rights of a party can be requested from the courts before the event that the party is trying to avoid, occurs.

[61] Before us, the respondents' principal submission also rests on the judgment in Syed Kechik and additionally a judgment of this court in *YAB Dato' Dr Zambry Abd Kadir & Ors v. YB Sivakumar Varatharaju Naidu; Attorney-General Malaysia (Intervener)* [2009] 4 CLJ 253; [2009] 4 MLJ 24 ('*Zambry*'),

[62] The facts of *Syed Kechik* were these. The appellant in that case deposed cogent reasons to believe that the Government of Sabah was attempting to deprive him of his status as a native of Sabah which was previously declared in his favour by the Native Court. He had also been a permanently resident in Sabah and had built his life there. He therefore filed a suit seeking declarations to the effect that he be declared an Anak Negeri of Sabah, that he has a valid permanent residence status and that any Entry Permit previously issued in his favour cannot be revoked.

[63] Against these prayers for such declaratory reliefs, the Federal Government which was party to the case argued that no such action had been taken to deprive the appellant of such rights (as alleged) and indeed the court below similarly found the matter to be premature and that the matter ought more properly to be dealt with under the special machinery of the Immigration Acts.

[64] This court unanimously found in favour of the appellant and held that he was entitled to the declaratory reliefs sought. His action was not premature, but more pre-emptive. In this regard, the following *dictum* of Suffian LP is instructive, at p. 103:

> In my view, the applicant has a real fear that he may be expelled from Sabah, and it is desirable for the court to declare whether or not the Federal and State Governments have a right to expel the applicant, **so that all parties concerned will know exactly where they stand**.
>
> (emphasis added)

[65] In the same case, Lee Hun Hoe (CJ Borneo) observed thus, at p. 107:

> It is the submission of appellant that he has no other remedy of establishing his right to reside in Sabah. The declaration sought is not as to his future right but as to his present right. There has been a threat to his right by official statement of the party in power. The threat has never been denied or withdrawn. A political party can only realise its objectives if it were in power. **He need not have to wait for something to happen before seeking the court's protection ... A declaratory order will eliminate anxiety of having to live under a cloud of fear**. In granting a declaration the court has to consider the utility of the declaration claimed and the usefulness of the declaration on the one hand as against the inconvenience and embarrassment that may result on the other hand. As to the determination of future right its importance for certain purposes is not in doubt, particularly when a mere declaration is usually the only remedy.
>
> (emphasis added)

[66] What is clear from the above *dicta*, which we consider to form the *ratio decidendi* of *Syed Kechik* is that the very utility of declaratory orders is to inform parties concerned "exactly where they stand" and that the affected party "need not have to wait for something to happen before seeking the court's protection". These pronouncements are entirely consistent with our locus classicus on declarations and declaratory reliefs in *Tan Sri Haji Othman Saat v. Mohamed Ismail* [1982] CLJU 2; [1982] 1 LNS 2; [1982] 2 MLJ 177 ('*Othman Saat*') wherein the same former Federal Court, at p. 179, reaffirmed the point that declarations may 'generate rights'.

[67] The exact same principle was considered and applied by this court in *Zambry*. In that case, the appellants were assemblymen of the Perak State Legislative Assembly who initiated the action for declaratory relief that their suspension from the State Assembly was null and void during the pendency of disciplinary proceedings against them. The argument opposing the action was that the appellants cannot seek such declarations because it was designed to frustrate the disciplinary proceedings against them. It was held that the appellants were entitled to seek such declarations of their legal rights. See: *Zambry*, at [30]-[32].

[68] In the instant case, the Court of Appeal held (at [81]) that the decisions of *Syed Kechik* and *Zambry* applied to the present respondents, mainly the second respondent, because he is seeking declarations on his position and rights under Act 366.

[69] It has been the respondents' principal stance from day one that they are only subject to Act 366 and the 1952 Regulations in their dispensation of Ivermectin for the treatment of their patients only. They claim that they are not subject to Act 368 and the 1984 Regulations in this regard. As such, it is their submission that the declarations are not designed to impede upon

or interfere with criminal investigations against the second respondent but rather, it is for them and all registered medical practitioners to know their rights and position under the law.

[70] On the authorities cited above and for the reasons that follow, we accept the respondents' argument and the decision of the Court of Appeal as entirely correct on the facts. As such, we find that the High Court was erroneous in holding that the respondents were attempting to interfere with the criminal investigations to the extent of the relief prayed for in the declarations. We must stress again here, that by 'declarations' we are referring only to the relief granted by the Court of Appeal.

[71] The respondents have not at all challenged the legality of the search and seizure nor have they suggested or asked for any relief to the effect that the second respondent ought not to be prosecuted or that he had not committed any offence. In respect of the first respondent, their learned counsel submits that they too, representing a body of qualified specialists and doctors have the right to determine the extent of the legal rights of all doctors to dispense Group B poisons and the extent of how such a right is limited, if at all, by Act 368 and the 1984 Regulations.

[72] The nature of the relief sought in this case is purely and entirely to move the court to exercise its most basic functions of judicial interpretation to determine the state of the law as regards Acts 366 and 368 and their respective Regulations (1952 and 1984).

[73] The law is settled beyond any dispute that it is only the courts that may make determinative findings of factual and legal rights. While it remains the Public Prosecutor's sole right to charge any person for an offence, such a power is exercised in accordance with written law. Where the law is unclear, it is only the courts who may finally determine the interpretation of that law or rule. Such a final determination would then also serve the effect of putting parties on notice on "exactly where they stand" in terms of their present and future rights – as determined in *Syed Kechik*.

[74] In line with the above authorities, we think the situation as regards declarations can be explained through the following analogy. Let us assume that a person named X rides into a public park on his bicycle where there is a sign that says 'it is an offence to bring or ride any vehicle into this park' and there is no definition of 'vehicle' in any law. With this, we can now posit the following five hypothetical scenarios.

[75] In the first hypothetical scenario, X has been threatened with an action against him for riding in the park with his bicycle or absent such a threat, X just wants clarity or comfort on whether he was in violation of the rule. As such, X initiates an action for a declaration that his bicycle is not a vehicle

within the meaning of the words employed in the park sign. X therefore seeks a declaration to ascertain his legal rights and to know "exactly where he stands". By the foregoing authorities, he can do this and the suit cannot be said to be frivolous or an abuse of process.

[76] In the second hypothetical scenario, it is not X but another private person who frequents the same park and who is of the opinion that 'vehicle' includes bicycles files a suit for a declaration that 'vehicle' includes 'bicycles'. This private person either does this to seek clarity on X's actions or because he wants to know what the law is. This, by virtue of the foregoing authorities cited, is permissible.

[77] In the third scenario, the same private person, offended by X's actions decides to take matters into his own hands. Instead of seeking a determination of the meaning of 'vehicle' and whether it includes 'bicycle' files a suit against X to declare that X has committed an offence by riding his bicycle in the park. For the reasons earlier explained, this is impermissible, and such a declaration cannot therefore be granted or much less, be entertained.

[78] In the fourth scenario, the Public Prosecutor decides to charge X with an offence of violating the rule in the public park sign. X's guilt cannot be determined by the civil standards applicable in an application for a criminal trial and as such, the only way he can be made to answer for his offence is by way of the Public Prosecutor, in his discretion, preferring a charge against him. Whether or not 'vehicle' includes 'bicycle' can and will be decided as a question of law in that trial as that would be the first judicial determination that must be made. Thereafter, any further judicial determination can be made on the evidence on whether X did, in fact, commit the offence beyond a reasonable doubt.

[79] In the fifth and final scenario, X is prosecuted for the offence in the manner described in the fourth scenario above. But, whether during the investigation stages, or during the pendency of the charge, X is entitled to file a civil action for a declaration to the effect that 'vehicle' in the sign does not include 'bicycle'. While the prosecution might take the position that 'vehicle' means 'bicycle' in the criminal proceedings, that question of interpretation of the law can be decided by the civil courts at any stage and X is entitled to have that question decided as a means to gauge "exactly where he stands".

[80] It would be appreciated at once that the fifth scenario (considered in light of all the other four scenarios) illustrates how there is a clear and distinct demarcation of powers between the prosecutor-executive and the judicial branch that is alone constitutionally empowered and tasked to interpret the law.

[81] In scenarios four and five above, it is clear that X may do one of two things. One, he may either raise the defence in the criminal proceedings that 'vehicle' cannot and does not include 'bicycle' in addition to presenting evidence exculpating him from any allegations that he did ride his bicycle in the park in offence to the sign. Yet, there is also his opportunity to clarify the state of the legal interpretation of the word 'vehicle' in separate civil proceedings for a declaration to the effect that such a word cannot include 'bicycle'.

[82] This is entirely consistent with our system of criminal law in that the accused must always be presumed innocent until proven guilty, and that the right to a fair trial must be preserved. This equation also factors into account the crucial detail that the accused must be given every opportunity to present his defence and to know the case that is made against him. This includes the right to know "exactly where he stands" in relation to the law.

[83] Naturally, if a judicial determination is made in the civil proceedings that 'vehicle' does not include 'bicycle', then any criminal case sought to be made against X would have no legal leg to stand on. But, that cannot by any measure be taken to mean that X is impeding upon or interfering with criminal proceedings that have or might be brought against him. If the determination is such that it is declared against X that 'vehicle' does include 'bicycle' in the context of that sign in the park, then X would know that such a defence is not available to him and he can elect either to plead guilty to the offence or plead not guilty and claim trial to attempt to exculpate himself of any charge preferred or any evidence adduced against him.

[84] In this entire assessment and prior to the making of any such determination of the meaning of the word 'vehicle', there is virtually nothing that potentially affects the criminal investigations. While the criminal court may be minded to stay the criminal proceedings pending the civil suit, there is nothing prohibiting the prosecution from pursuing investigations against X, questioning eyewitnesses or taking any statements that can help support an eventual prosecution.

[85] If the declaration is made against X's favour, the prosecution can then stand firm on its resolve to prosecute X and X in turn, will (as stated earlier) have notice that the defence that the interpretation of 'vehicle' does not include 'bicycle' is no longer available.

[86] We indicated earlier that the appellants' submission on the law and their interpretation of the cases they have cited such as *Lim Kit Siang* as well as the limits of declaratory judgments, is correct. However, we find that the appellants' application of such law and principles to the facts of this case is entirely misplaced.

[87] For the reasons that have been stated in our analysis above, while *Syed Kechik* and *Zambry* do not on their facts concern the grant of declarations pending criminal charges or investigations, we hereby hold that their collective *ratio decidendi* extends to and applies mutatis mutandis to a case, such as this one, where the person(s) so affected seek(s) to the extent clarify or determine his or their legal rights or position.

[88] We accept the respondents' submission that the declarations do not impede upon or interfere with any criminal investigations and that the declarations will assist them in clarifying their legal rights *vis-à-vis* Acts 366 and 368 and their attendant Regulations. The facts of the present case are therefore akin to the fifth hypothetical scenario earlier elaborated. Further, ss. 18, 19 and 21 of Act 366 themselves specifically contain procedures and principles which all registered medical practitioners must follow and to the extent that the criminal investigations relate to this, they remain open and unimpeded.

[89] We therefore uphold the decision of the Court of Appeal as correct in reversing the High Court on any finding that such declarations are an abuse of process or frivolous and/or vexatious.

[90] Consequently, leave question 1 is answered in the affirmative.

Statutory Construction

Act 366 And The 1952 Regulations

[91] The next aspect of the case concerns the main issue, which is perhaps substantively the most important to the OS. This concerns the statutory construction of Acts 366 and 368, and their respective Regulations 1952 and 1984.

[92] The preamble to Act 366 clarifies its purpose being thus:

> An Act to regulate the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons.

[93] As was set out earlier, 'poisons' is a specific legal term referred to in the Act for purposes of regulation of such items that have been defined in s. 2 to mean "any substance specified by name in the first column of the poisons list and includes any preparation, solution, compound, mixture or natural substance containing such substance, other than an exempted preparation or an article or preparation included for the time being in the Second Schedule".

[94] The pillar of Act 366 is therefore the poisons list which is contained in the First Schedule.

[95] The poisons list is, in turn, split into Part I and Part II. Part I is further split into six categories or 'groups' beginning in the order of Group A until Group F. Ivermectin in 'all preparations' is included and referred to in the poisons list, First Schedule as a Group B poison.

[96] We will note here that the preamble to Act 366 is comprehensive in that it covers a wide range of activities in relation to 'poisons'. In this regard, the structure of Act 366 contains specific sections that appear to deal with all the categorised purposes of the Act in its preamble.

[97] Correspondingly, s. 8 deals with importation; s. 13 with possession; s. 11 with manufacture; s. 12 with compounding; s. 9 with storage (and related matters); s. 10 with transport; ss. 15 to 18 with sale (through various methods).

[98] Specifically, s. 15 concerns the sale of poisons by wholesale and s. 16 with sale by retail. Sections 17 and 18 in turn relate to certain prohibitions on sale or supply under ss. 15 and 16. Before addressing s. 19, we specifically observe that the set of provisions in ss. 20 until 23 deal respectively with poisons in Group A to Group D.

[99] The following definitions of "sale" and "supply" in s. 2 of Act 366 are also important, namely:

> "sell" or "sale" includes barter and also includes offering or attempting to sell;
>
> "supply" includes the supply of commercial samples and dispensed medicines, but does not include the direct administration by or under the immediate personal supervision of a registered medical practitioner or registered dentist of a poison or medicine to his patient in the course of treatment where such administration is authorized under section 19;

[100] Section 2 also defines "wholesale" and "retail sale" as follows:

> "retail sale" means any sale other than a wholesale sale;
>
> "wholesale" means a sale to any person who intends to sell again and any sale by a licensed wholesaler authorized by paragraphs (d) to (k) inclusive of section 15(2).

[101] We come then to s. 19 which is the principal provision upon which the respondents rely. Specifically, s. 19(1)(a) unequivocally stipulates, in part relevant to the present case, that a registered medical practitioner may sell, supply or administer any Group B poison to his patient for the purposes of the medical treatment of such patient only. The operative words in relation to any registered medical practitioner are "sell, supply or administer". For clarity, we reproduce the provision again as follows:

A Supply of poisons for the purpose of treatment by professional men

19. (1) Any poison other than a Group A Poison may be sold, supplied or administered by the following persons for the following purposes:

(a) a registered medical practitioner may sell, supply or administer such poison to his patient for the purposes of the medical treatment of such patient only; ... .

[102] And so, to decipher the meaning of the three words "sell, supply or administer", we must have regard to the statutory definitions of Act 366 and the structure of its provisions earlier highlighted.

C **[103]** We have perused the descriptions of "sale by wholesale" and "sale by retail" in ss. 15 and 16 (for brevity we will not reproduce), and s. 18(1)(c) of Act 366 which provides thus:

Restriction on the sale or supply of Part I poisons generally

18. (1) Part I Poison shall not be sold or supplied to any person except:

(a) ...

(b) ...

(c) as an ingredient of a dispensed medicine, by a registered medical practitioner, registered dentist or registered veterinary surgeon in accordance with section 19; or ... .

[104] We also look at s. 21 of Act 366 (which deals specifically with Group B poisons) which stipulates as follows in sub-s. (1)(b):

Group B poisons

21. (1) Group B Poison shall not be sold or supplied by retail to any person except:

(a) ...

(b) by a registered medical practitioner, registered dentist Division I or registered veterinary surgeon selling or supplying the same in accordance with section 19; or.

[105] From the rather confusing arrangement of the provisions, our analysis points to the conclusion that under s. 19(1)(a) of Act 366, registered medical practitioners may issue Group B poisons to any person either by sale or supply (which would involve a financial transaction) or administer (which involves direct administration and personal supervision) all on the condition that such a person is that registered medical practitioner's patient and that such "sale, supply or administration" is for the treatment of that person as a patient.

[106] We are further fortified in this view by reason of the fact that s. 21(2) (which section deals with Group B poisons) contains an entire procedure on prescriptions and how such poison (considered medication) is sold or supplied to the patient for the treatment of that patient.

[107] As such, because Ivermectin is classified as a Group B poison in the First Schedule (and it is not therefore a Group A poison), it would follow as per s. 19(1)(a) of Act 366 that any registered medical practitioner may sell, supply or administer Ivermectin to his patient for the treatment of his patient only and only by reason of the fact that the person so selling, supplying or administering Ivermectin is a registered medical practitioner.

[108] We therefore agree with the respondents' submission that under s. 19 of Act 366, and having regard to the scheme of that Act, the second respondent (as are all other registered medical practitioners) is allowed by law to dispense Ivermectin to his patients provided that such dispensation is for the purposes of that patient's treatment only.

[109] In our view, the 1952 Regulations have little bearing on this interpretation because the rights to dispense (sell or supply) and administer Ivermectin as a Group B poison are substantively determined by Act 366 as the parent or primary legislation to the 1952 Regulations. Further, the 1952 Regulations deal more with technical matters mainly such as storing, labelling, packaging and import of poisons, and not with the substantive rights of registered medical practitioners that are regulated expressly by ss. 19 and 21 of Act 366.

[110] We will now consider the appellants' arguments on the interpretation to be afforded to Act 366 in light of Act 368 and its 1984 Regulations.

Act 368 And The 1984 Regulations

[111] It is the appellants' case that Ivermectin is not registered for human use and is an unregistered drug that cannot therefore be prescribed to human patients for that purpose. They submit that the decision of the Court of Appeal has the effect of legitimising the use of Ivermectin for the treatment of COVID-19 notwithstanding that Ivermectin (as an active ingredient) has not been registered with the Drug Control Authority (PBKD), and that if at all Ivermectin has been used for such a purpose, it has only seen such limited use in clinical trials.

[112] It is the appellants' submission that Act 366 cannot be read alone and must be read subject to other laws on the subject, in this case, Act 368 and its 1984 Regulations. It is therefore their submission that the Court of Appeal failed to pay sufficient consideration to the regime in Act 368.

[113] The crux of the appellants' submission rests on the fact that Ivermectin "can also be categorised as a drug" to the extent that it is used to alleviate, treat, cure or prevent a disease or a pathological condition or symptoms of a disease in humans.

[114] We now consider Act 368.

[115] The preamble of Act 368 defines it purpose as:

> An Act relating to the sale of drugs.

[116] Section 2 of Act 368 defines "drug" as meaning to include:

> any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose;

[117] "Medicinal purpose" is in turn defined to include:

> any of the following purposes:
>
> (a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;
>
> (b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
>
> (c) contraception;
>
> (d) inducing anaesthesia;
>
> (e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
>
> (f) controlling body weight;
>
> (g) general maintenance or promotion of health or well-being;

[118] Section 2 continues with its definitions ending with the following definition of "sale or sell" where it stipulates that it:

> includes barter and exchange and also includes offering or attempting to sell or causing or allowing to be sold or exposing for sale or receiving or sending or delivering for sale or having in possession for sale or having in possession any drug knowing that the same is likely to be sold or offered or exposed for sale.

[119] Once a "drug" is determined under Act 368, reg. 7 of the 1984 Regulations stipulates in material part in sub-regulation (1) that:

> Prohibition against manufacture, sale, supply, importation, possession and administration
>
> 7. (1) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administer product unless

(a) the product is a registered product; and

(b) the person holds the appropriate licence required and issued under these Regulations.

[120] By reason of the conjunction "and" used in the above provision, the appellants submit that the two requirements are cumulative. Both must be fulfilled before any person can manufacture, sell, supply, import or possess or administer any such product.

[121] The appellants then rightly highlight sub-reg. 15(2)(c) of the 1984 Regulations that exempts registered medical practitioners from the requirement of having a license, as follows:

Exemptions and savings

15. (1) ...

(2) The requirement of regulation 7(1) **as regards a licence to supply or manufacture** does not apply to the dispensing, of any drug for the purpose of it being used **for medical treatment of a particular patient** or animal, by the following persons and in the following circumstances:

(a) ...

(b) ...

(c) **a fully registered medical practitioner** or a dental practitioner or a veterinary practitioner or a person working under the immediate personal supervision of such a practitioner **if the drug in question is for the use of such practitioner or of his patients**.

(emphasis added)

[122] Accordingly, the appellants submit that the main issue here is that while the second respondent is exempted from the license requirement in sub-reg. 7(1)(b) by virtue of sub-reg. 15(2)(c), he and other registered medical practitioners remain bound by the requirement of sub-reg. 7(1)(a) for which there is no statutory exemption against its requirement that the product must first be a "registered product".

[123] It is not disputed that under Act 368 and the 1984 Regulations, there is no drug with Ivermectin as an ingredient suitable for the consumption of human patients.

[124] In answer to these arguments, the respondents' position is simply that Act 368 does not apply, not only in relation to the second respondent, but to all registered medical practitioners who are only subject to Act 366 in their dispensation of Ivermectin to their patients and for the use of the treatment of those patients only.

[125] In relation to the application of Act 366, while the appellants have minimally conceded that Act 366 "has never catered or dealt with the requirement of the product itself to be registered" they assert that "the so called right vested under Act 366 in relation to sale and supply of Ivermectin is still subject to the provisions of Act 368 and 1984 Regulations."

[126] The respondents therefore stress the point that Act 366 overrides Act 368 insofar as the right to dispense Group B poisons is concerned and that reg. 7 of the 1984 Regulations being a subsidiary legislation cannot supplant or replace primary legislation in Act 366. It is also their submission that Act 368 is a specific law passed only for a certain purpose as opposed to the all-encompassing Act 366.

[127] It has also been highlighted to us that both Acts 366 and 368 are statutes of even year. Act 366 was enforced on 1 September 1952 while Act 368 only two months later on 1 November 1952. They are in essence in *pari materia*.

[128] The Court of Appeal accepted the respondents' submission on the non-applicability of Act 368 to the present facts. In this regard, the Court of Appeal's findings in its written judgment are:

(i) when Parliament enacts laws, especially laws within the same year and for similar purposes, such that these laws form a system or code of legislation, these laws must be construed harmoniously. See: [60]-[63]; and

(ii) the autonomous rights of registered medical practitioners to dispense Group B poisons (including Ivermectin) is statutorily conferred to them by ss. 18, 19 and 21 of Act 366. The only abridgement of this right (in the manner suggested by the appellants) is through regs. 7 and 15 of the 1984 Regulations. The Court of Appeal in this respect held that a subsidiary legislation cannot curtail the rights conferred by primary legislation.

[129] For the point in (i) mentioned above, the Court of Appeal also relied on its prior judgment in *Tey Por Yee & Anor v. Protasco Bhd & Other Appeals* [2020] 5 CLJ 216; [2021] 1 MLJ 76 wherein the Court of Appeal cited with approval certain treatises, as follows:

> [99] The meaning of the phrase 'in *pari materia*' was extensively discussed in *Shah & Co v. State of Maharashtra* 1967 AIR SC 1877, where Vaidialingam J said, at pp 1882-1883:
>
> > (21) We have been referred to certain passages in certain text books, as well as in certain decisions, to show, under what circumstances, statutes can be considered to be in *pari materia*, and the nature of the construction to be placed on such statutes.

> Sutherland, in '*Statutory Construction*', 3rd Ed, Vol 2, at p 535, states: Statutes are considered to be in *pari materia* - to pertain to the same subject matter - when they relate to the same person or thing, or to the same class of persons or things, or have the same purpose or object.

The learned author, further states, at p 537:

> When the legislature enacts a provision, it has before it all the other provisions relating to the same subject matter which it enacts at that time, whether in the same statute or in a separate act. It is evident that it has in mind the provisions of a prior act to which it refers, whether it phrases the later act as an amendment or an independent act. Experience indicates that a legislature does not deliberately enact inconsistent provisions when it is cognizant of them both, without expressly recognizing the inconsistency.

The canon of construction, under these circumstances, is stated by the author, at p 531:

> Prior statutes relating to the same subject matter are to be compared with the new provision; and if possible by reasonable construction, both are to be so construed that effect is given to every provision of each. Statutes in *pari materia* although in apparent conflict, are so far as reasonably possible construed to be in harmony with each other.

In Craies, on '*Statute Law*', 6th Edition, at p. 133, it is stated:

> An author must be supposed to be consistent with himself, and, therefore, if in one place he has expressed his mind clearly, it ought to be presumed that he is still of the same mind in another place, unless it clearly appears that he has changed it. In this respect, the work of the legislature is treated in the same manner as that of any other author, and the language of every enactment must be construed as far as possible in accordance with the terms of every other statute which it does not in express terms modify or repeal ... It cannot be assumed that Parliament has given with one hand what it has taken away with the other.

[130] We entirely agree with the above passage as reflecting the correct application of principles relating to statutory construction especially in relation to statutes that are in *pari materia* such as Acts 366 and 368.

[131] Upon a wholesome analysis of Act 366, we find that it is a complete code on all matters relating to poisons in the manner suggested in its preamble. It was passed with the overt intention of regulating and overseeing all manner of dealings with poisons including their sale and supply. By virtue of ss. 19 and 21 of Act 366, there is an express exemption in favour of registered medical practitioners to dispense, in their professional judgment, Group B poisons for the treatment of their patients only. A prescription regime is also put in place to ensure that such dispensations or supplies are done in accordance with the law.

[132] Unlike Act 366, Act 368 is only confined to the sale of 'drugs'. Unlike Act 366 which specifically and comprehensively enlists poisons by parts and further by groups and further still by methods of preparation (including Ivermectin), Act 368 is comparatively a scantier legislation that makes no specific mention of any form of drugs except by way of a loose definition of the term "drug" in its s. 2.

[133] We notice that Act 368 pertains more to the establishment of offences against the sale of drugs and the powers of officers in relation to such offences. There is absolutely nothing in Act 368 that speaks to all manner of handlings and dealings of poisons.

[134] We further notice that in Act 368, there is absolutely no mention or hint of reference whatsoever to "registered medical practitioners" in the manner clearly and lucidly alluded to in Act 366. Thus, if we were to accept that the two Acts 366 and 368 together constitute a regulatory mechanism for drugs and poisons – which suggestion is also made by the appellants - the silence by lack of such a reference in Act 368 paints the impression that Parliament had, in passing both laws in the same year, intended that insofar as registered medical practitioners are concerned it is Act 366 that should apply.

[135] Putting it another way, Act 366 positively asserts a right vested in ss. 18, 19 and 21 to registered medical practitioners to sell, supply and administer Group B poisons to their patients for that patient's treatment only and specifically enumerates those poisons (and their manner of preparations) patently in the First Schedule. Act 368 appears to disregard any such mechanism for it is entirely silent on the rights of registered medical practitioners to supply 'drugs' (as opposed to expressly enumerated 'poisons') and what exactly can ostensibly be ascertained as 'drugs' in the absence of any expressly enumerated provisions in Act 368.

[136] Accordingly, we find that Act 368 has no application insofar as the present facts are concerned that is, in relation to the rights of a registered medical practitioner to sell, supply or administer Group B poisons as per ss. 18, 19 and 21 of Act 366.

[137] This only leaves us with the 1984 Regulations the fate of which can be quickly decided since its parent Act, Act 368 has no nexus to the respondents in relation to Group B poisons.

[138] It is a tried and tested rule that subsidiary legislation cannot give or take away powers and rights that are conferred by its parent Act or any other primary legislation. In this sense, Act 366 is a primary legislation whereas the 1984 Regulation is only a subsidiary legislation and that too to Act 368; not Act 366.

[139] There are too many cases to explain this principle but it would suffice if we referred to only one of those cases.

[140] In *Ang Ming Lee & Ors v. Menteri Kesejahteraan Bandar, Perumahan Dan Kerajaan Tempatan & Anor And Other Appeals* [2020] 1 CLJ 162; [2020] 1 MLJ 281 ('*Ang Ming Lee*'), this court held that the relevant housing legislation only conferred power to the Minister to amend scheduled contracts which included amending them to extend time for completion of housing projects by developers. In that case, the impugned subsidiary legislation enacted under that primary housing legislation purported to accord such power to the comptroller. This was deemed *ultra vires* its parent Act.

[141] The rationale for treating subsidiary legislation in this way is best described in the words of Zawawi Salleh FCJ who in *Pihak Berkuasa Tatatertib Majlis Perbandaran Seberang Perai & Anor v. Muziadi Mukhtar* [2020] 1 CLJ 1; [2020] 1 ILR 328; [2020] 1 MLJ 141, said ('*Muziadr'*):

> [82] ... [Subsidiary legislation must yield to the primacy of the parent Act and must operate in the context of the parent Act. As the stream cannot rise above its source, so the subsidiary/delegated legislation cannot be broader than the parent Act.

[142] As noted, Act 366 is not the parent Act of the 1984 Regulations, and in any case, there is no challenge by the respondents on the validity of the 1984 Regulations. There is, in other words, no allegation of *ultra vires*. And clearly, there is nothing outwardly *ultra vires* between the 1984 Regulations and Act 366 as the former makes no reference to the latter.

[143] The problem in this case only arises by reason of the fact that the appellants seek to interpret the 1984 Regulations in such a way that it can be read as restricting the scope of Act 366 as regards the right of registered medical practitioners to "sell, supply or administer" non-group a poisons.

[144] We find that even in the absence of an allegation of *ultra vires*, the substantive principle remains the same that subsidiary legislation cannot displace primary legislation whether or not that primary legislation is its parent Act. Such a strained and legally incoherent reading can, in our view, be avoided by reading down the impugned subsidiary legislation against the said primary legislation.

[145] Preferring such an approach, we find that just as Act 368 has no bearing on the aforementioned express rights conferred to registered medical practitioners by ss. 18, 19 and 21 of Act 366, so too Regulation 1984 (being subsidiary legislation) cannot purport to limit the application of the provisions of ss. 18, 19 and 21 of Act 366 – a primary legislation.

[146] If the appellants' interpretation of reg. 7 of the 1984 Regulations *vis-à-vis* the specific provisions of ss. 18, 19 and 21 of Act 366 is accepted, it would mean that a registered medical practitioner is on the one hand granted a right to sell, supply or administer a Group B poison (including Ivermectin) by primary legislation only then to have that right taken away by the 1984 Regulations because Ivermectin (or some other Group B poison) as a 'poison' or ingredient appears in a drug that is not a "registered product" per the subsidiary legislation provision in sub-reg. 7(1).

[147] While Act 368 is generally a legislation intended for a more specific purpose, *ie*, the sale of drugs only as opposed to the wide purposes of all matters relating to poisons in Act 366, ss. 18, 19 and 21 of Acts 366 are nonetheless the more specific provisions that expressly confer specific rights unto registered medical practitioners to "sell, supply and administer" Group B poisons to their patients for their treatment only which is a specific regime that Act 368 (despite its specificity) does not cater for. As for the 1984 Regulations, being subsidiary legislation, they do not and cannot have sufficient legal force to override the primary provisions of Act 366's ss. 18, 19 and 21 even if for argument's sake the said 1984 Regulations had been promulgated under Act 366 itself and not Act 368.

[148] In the High Court right up until before us, the appellants have not once disputed the interpretation of the relevant provisions in Act 366 in the manner advanced by the respondents. Their only singular substantive suggestion appears to be that while such rights exist in Act 366, these rights are further subject to a requirement that the said drug must first be a registered product under the 1984 Regulations.

[149] For the reasons stated at length above, we cannot agree with such a constrained reading of the applicable provisions and consequently, the Court of Appeal was correct to reverse the findings of the High Court.

Interference With Executive Policy

[150] The final issue in this appeal that arises as a result of the insinuations in leave questions 3, 4, 5 and 6 and the direct submissions on this issue by the appellants is whether the respondents are inviting judicial interference upon executive policy by effectively legitimising the use of Ivermectin for the treatment of COVID-19.

[151] In support, the appellants have cited certain decisions which includes among them: *SD v. Royal Borough Of Kensington And Chelsea* [2021] EWCOP 14 ('SD'); *Athvale v. New South Wales* [2021] FCA 1075 ('*Athvale*'); *Kassam And Others v. Hazzard And Others* [2021] 393 ALR 664 ('*Kassam*'); and *Clarence Ng Chii Wei & Ors v. Menteri Kesihatan & Ors* [2022] 1 CLJ 247 ('*Clarence Ng*').

[152] It is the appellants' position that all the foregoing authorities collectively advance the proposition that the courts have no business considering among other things, the efficacy of Ivermectin as a treatment for or preventive measure against COVID-19. The merits and demerits of that argument or any determination of such matters are Executive questions that are best addressed by policymakers and Parliament.

[153] With respect, we find yet again that though the appellants have correctly cited these cases for the legal propositions they make, the appellants have misapplied these principles to the facts of the present case which do not whatsoever concern any questions of policy. In that sense, all the cases cited by the appellants can be readily distinguished.

[154] SD was a suit where the English and Welsh Court of Protection considered the applicant-daughter's application pertaining to the welfare of her mother, V – an elderly lady living in a welfare home. The primary issue in that case was whether it was in V's best interests to receive the COVID-19 vaccine and against this measure, one of the applicant's arguments was the availability and efficacy of Ivermectin as a treatment for and preventive measure against COVID-19. In deciding that V was required to obtain the vaccine, the English and Welsh Court of Protection held that the courts are not the right forum for the ventilation of medical controversies and to consider the merits and demerits of Ivermectin. See: SD, at [29] to [31].

[155] *Athvale* was a suit in which the applicants sought injunctive relief against the State's policy on social distancing and gatherings which they asserted interfered with the celebration of certain religious events. In their argument, the applicants relied on the opinion of an expert witness who suggested that Ivermectin was a cheap and effective treatment against COVID-19 presumably to bolster their argument that such policy measures designed to curb the spread of COVID-19 were unnecessary. On this point, the Federal Court of Australia effectively held that whether or not Ivermectin is a suitable remedy for COVID-19 is not a question for the courts to decide. It is a matter for the State to determine as it involves "evaluative judgment with a heavy political and policy content'. See: *Athvale*, at [79].

[156] The issue in *Kassam* was similar to the two cases we just referred to. In that case, measures were imposed such that certain workers were prevented from leaving certain areas of concern and people were further prevented from working in construction, aged care, and education sectors, except for those who had been vaccinated with an approved COVID-19 vaccine. The argument again relied on the same expert evidence in *Athvale* to the effect that Ivermectin was a suitable alternative to the approved vaccines to prevent and treat COVID-19. The Supreme Court of New South Wales rejected these arguments for principally the same reasons as SD and *Athvale*. The following dictum of the Supreme Court is relevant, at p. 668:

> [I]t is important to note that it is not the Court's function to determine the merits of the exercise of the power by the Minister to make the impugned orders, much less for the Court to choose between plausible responses to the risks to the public health posed by the Delta variant. It is also not the Court's function to conclusively determine the effectiveness of some of the alleged treatments for those infected or the effectiveness of COVID-19 vaccines especially their capacity to inhibit the spread of the disease. These are all matters of merits, policy and fact for the decision maker and not the Court.

[157] In *Clarence Ng*, the High Court dismissed the plaintiff's application for judicial review to the extent that it sought to quash the National Immunisation Program for teenagers in Malaysia on the grounds that the said program ought to be put on hold pending the conclusion of clinical trials on Ivermectin as a suitable treatment for COVID-19 as opposed to vaccination. In his assessment of the case, Wong Hok Chong JC concluded among others, the same as the earlier decided cases that whether or not Ivermectin is a suitable alternative as suggested is a question of Government policy – and one that cannot be determined by the judicial branch.

[158] We find that all the above reasons are correct and are entirely applicable in line with our constitutional mechanism of separation of powers.

[159] Yet, we find that these principles have absolutely no bearing on the present case as we agree with the respondents' submissions, as did the Court of Appeal, that the present case is not concerned with the efficacy of Ivermectin *vis-à-vis* COVID-19 but only with the substantive right of the respondents and other registered medical practitioners to dispense the same to their patients for their treatment only as per Act 366. We reiterate that we are only concerned with the interpretation of the provisions of Act 366 and its 1952 Regulations as against the application of Act 368 and its subsidiary legislation in the 1984 Regulations.

[160] Learned SFC for the appellants, Tuan Rahazlan Affandi, repeatedly made the point in his oral submission on how the Court of Appeal, by granting in its judgment the declarations, has in effect "legitimised" the use of Ivermectin (though a Group B poison) and which they submit is a "drug" capable of restriction by the 1984 Regulations, for the treatment/prevention of COVID-19, against Government policy.

[161] In our careful assessment of the facts and circumstances of this case, what has actually happened is that the Government, perhaps rightly concerned about fallacious or suspicious treatment measures for COVID-19, was wary of the unproved use of Ivermectin. There is no doubt that the Government had its hands full managing a major international public health crisis; hospitals with not enough beds and support equipment for dying or critical patients; doctors and nurses who were beyond exhausted; and a

public that was against many of the measures introduced including vaccinations, and the restrictions on movement and gatherings. We can by no means trivialise any of these matters.

[162] However, in relation to Ivermectin, to curb its use, the Government took it upon itself to decide that Act 368 and its 1984 Regulations can be used as a means to restrict the right accorded to registered medical practitioners to dispense Group B poisons (including Ivermectin) as per Act 366 and to prevent any reliance on Ivermectin for the treatment and/or prevention of COVID-19. Unfortunately, their reliance on, and application of, Act 368 and the 1984 Regulations, as has been established above, is erroneous and misplaced on all accounts of statutory construction.

[163] If it stems from the judgment of the Court of Appeal or even our judgment upholding the Court of Appeal's decision that Act 368 and the 1984 Regulations cannot restrict the right of registered medical practitioners in Act 366 to dispense Group B poisons in the manner suggested by the appellants, and that this has the effect of allowing registered medical practitioners to dispense Ivermectin (a Group B poison) for the treatment/prevention of COVID-19, then this is not a "legitimisation" of Ivermectin for such purpose against Government policy. Rather, it is for the Government an unwanted result of the proper interpretation of the regulatory scheme collectively contained in the four statutes, *ie*, Acts 366, 368 and their respective 1952 and 1984 Regulations.

[164] In this sense, if at all the Government was cautious of the fact that Ivermectin was not as at that time suitable for use against COVID-19, learned counsel for the respondents, Dato Dr Gurdial, has rightly pointed out that the Minister ought to have exercised his discretion, in consultation with the Poisons Board, to vary the poisons list as he is allowed to do, under s. 6 of Act 366, as follows:

> Power of Minister to amend poisons list
>
> 6. The Minister may, from time to time, after consultation with the Poisons
>
> Board by order notified in the Gazette, add to, remove from or reinstate in the poisons list any substance as he may deem fit or proper, or remove from transfer to or include in any column of the poisons list any poison, or exempted preparation or amend any definition of any poison or exempted preparation contained in such list or in any column thereof.

[165] As such, no matter how noble and well-founded the appellants' intention behind the fear of misuse of Ivermectin, these noble intentions cannot justify subverting the law by according a strained reading of clear statutory rights accorded to registered medical practitioners by Act 366.

A **[166]** We also hasten to add that it has not escaped our attention that the appellants have pointed out numerous averments by the respondents in all their affidavits filed in respect of the OS where the respondents positively suggest that Ivermectin is necessary for the treatment of COVID-19 specifically prophylaxis and viral infection. We assure all parties concerned
B that none of these assertions have coloured our minds on the efficacy of Ivermectin as a suitable treatment for COVID-19 which we hold is a non-issue in this case.

[167] All things considered, it is not the Courts but Act 366 (properly interpreted) that grants the right to registered medical practitioners to
C dispense Ivermectin as a Group B poison and if they continue to do so in accordance with Act 366, even if for the treatment/prevention of COVID-19, then this continues to happen because of the appellants' failure to enforce more suitable legal mechanisms to curb the practice pending any proper determination of Ivermectin's ability to treat or prevent COVID-19
D as the respondents and others like them claim it can.

[168] To the extent that the appellants suggest that they may rely on Act 368 and the 1984 Regulations to disallow dispensation of Ivermectin under Act 366, we have decided that we did not agree with that interpretation – and this has no bearing on any government policy of Ivermectin as a drug/
E medicine/ingredient itself.

Conclusion

[169] For the reasons stated above, leave question 1 is answered in the affirmative. As for the rest of the leave questions (2 to 6), we find that they
F bear no nexus to the facts of the present case and arise instead, from a misplaced application and consideration of trite legal principles. For that reason, we decline to answer leave questions 2 to 6.

[170] In the premises, the appeal is dismissed and we uphold the judgment of the Court of Appeal including the order it has already made in respect of
G costs.

[171] Insofar as these proceedings are concerned, since this litigation concerns significant public interests, there shall be no order as to costs in respect of the proceedings in this court.

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